88-1446

Supreme Court, U.S.
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No.

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1988

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NEW YORK STATE OPHTHALMOLOGICAL SOCIETY, CALIFORNIA ASSOCIATION OF OPHTHALMOLOGY, *et al.*,

*Petitioners,*

*v.*

OTIS R. BOWEN, Secretary, United States Department of Health and Human Services,

*Respondent.*

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## PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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March 2, 1989

## QUESTION PRESENTED

Whether the government may prevent a Medicare patient facing cataract surgery from selecting, and using his or her own money to pay for, the lawful services of an assistant at surgery in order to reduce the risks of unpredictable surgical complications solely because the government believes that the economic cost to the patient outweighs the conceded potential medical benefits of the assistant.

## PARTIES TO THE PROCEEDING

In addition to the parties listed in the caption, the following are additional petitioners:

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Sherwin H. Sloan, M.D.
William M. McCarty, M.D.
Robert D. Broderick, M.D.
Alan M. Levine, M.D.
Elliott Feinman, M.D.
Juliette Dufort
F. Dan Foltz
Helen Neill
Mortimer Rosenberg
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**PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT**

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Petitioners, the New York State Ophthalmological Society, California Association of Ophthalmology, Michael A. Sansone, M.D., Sherwin H. Sloan, M.D., William M. McCarty, M.D., Robert D. Broderick, M.D., Alan M. Levine, M.D., Elliott Feinman, M.D., Juliette Dufort, F. Don Foltz, Helen Neill, Mortimer Rosenberg, and John Bailey, petition for a writ of certiorari to review the judgment and opinion of the United States Court of Appeals for the District of Columbia Circuit in this case.

## OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-33a) is reported at 854 F.2d 1379.[1] The opinion of the United States District Court for the District of Columbia (App., *infra*, 38a) is unreported.

## JURISDICTION

The judgment of the court of appeals was entered on August 19, 1988. The order of the court of appeals denying rehearing *en banc* was entered on December 2, 1988. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

## CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Fifth Amendment to the United States Constitution provides in pertinent part:

> "No person shall . . . be deprived of life, liberty, or property without due process of law. . . ."

42 U.S.C. § 1395y provides in pertinent part:

> "(a) Items or services specifically excluded
>
> Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services—
>
> . . . . (15) which are for services of an assistant at surgery in a cataract operation unless, before the surgery is performed, the appropriate utilization and quality control peer review organization (under part B of

[1] The appendix to this Petition is cited throughout as "App." The record before the court of appeals, as contained in a joint appendix prepared by the parties, is cited either as "J.A" or by reference to the full name of the cited document.

subchapter XI) or a carrier under section 1395u of this title has approved of the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition. . . ."

42 U.S.C. § 1395u provides in pertinent part:

"(k) Sanctions for billing for services of assistant at cataract operations

(1) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part for charges for services as an assistant at surgery for which payment may not be made by reason of section 1395y(a)(15) of this title, the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section. . . .

(2) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part for charges that includes a charge for an assistant at surgery for which payment may not be made by reason of section 1395y(a)(15) of this title, the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section. . . ."

## STATEMENT OF THE CASE

### A. The Medicare Program

In 1965, Congress enacted the Health Insurance for the Aged Act, 42 U.S.C. §§ 1395 *et seq.*, popularly known as Medicare. Medicare is not a need-based program. Instead, it provides health insurance to all persons 65 or older and to certain disabled individuals.

The Medicare program is composed of two distinct insurance plans. Part A, 42 U.S.C. §§ 1395c-1395i-2, covers services provided by hospitals and other institutional providers. Part B, §§ 1395j-1395w, establishes a voluntary supplemental medical insurance program covering certain physician

services and other health services. This case involves Part B exclusively.

Generally, the Medicare program pays 80% of the "reasonable charge" for those physician services covered under Part B. 42 C.F.R. § 405.245. For physician services that are not covered under Part B, Medicare pays no portion of the bill and the bill need not be submitted to Medicare. Until enactment of the statutory amendment at issue here, the Medicare program had never been used to regulate provision of lawful medical services for which Medicare does not offer payment.

**B. The Challenged Statutory Amendment**

The need for cataract surgery is quite common among older persons. *See* 854 F.2d at 1381. While in most cases emergency complications do not occur during the surgery, in some cases they do. It is usually impossible to predict in advance specifically which cataract operations will, and which will not, result in complications.[2] In order to be prepared to deal with such unpredictable occurrences, many ophthalmologic surgeons recommend and utilize a cataract surgical assistant ("CAS"). There is disagreement among responsible physicians, however, concerning the extent to

[2] In connection with preliminary injunction proceedings before the district court, Michael M. Dunn, M.D., Chairman of the Department of Ophthalmology of the New York Eye & Ear Infirmary, and also Chairman of the Department of Ophthalmology at New York Medical College, submitted an affidavit quantifying the frequency of unpredictable complications occurring during cataract surgery. He attested that his review of 13,000 cataract operations performed at New York Eye and Ear Infirmary during the preceding two years showed that while complications during cataract surgery occurred on the average of 30.9 times per thousand cases, "in less than one-tenth of one percent of the cases could a complication have been predicted" in advance. (J.A. 87-88).

which the presence of a cataract surgical assistant during surgery is cost-effective over the entire universe of patients.[3]

In 1985, Congress entered one aspect of this dispute by enacting certain amendments to the Medicare Act as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), Pub. L. No. 99-272. Section 9307(a) of COBRA provides that Medicare will not provide any reimbursement "for services of an assistant at surgery in a cataract operation unless, *before the surgery is performed*, the appropriate utilization and quality control peer review organization . . . or a carrier . . . has approved of the use of such an assistant in the surgical procedure *based on the existence of a complicating medical condition.*" 42 U.S.C. § 1395y(a)(15) (emphasis supplied). Thus, if a qualifying "complicating medical condition" cannot be demonstrated prior to the cataract surgery, the Medicare program will not pay for CAS services.[4] This is so even

[3] CAS services are lawful in every jurisdiction and are so common as to constitute the required standard of care in such major medical centers as New York and California. (J.A. 94, 99). To be sure, not all ophthalmologists use CAS services or believe them to be essential. As observed in the report of the Office of the Inspector General ("OIG"), referred to by the court of appeals majority (854 F.2d at 1381, 1391), there is a diversity of practice among reasonable physicians. Specifically, the OIG report found that in nine out of 29 states surveyed, the use of CAS services was not the prevailing practice. 854 F.2d at 1381. A diversity of practice does not mean, however, as the methodology of the OIG report assumes, that any practice which goes beyond the lowest common denominator must be "unnecessary." Rather, "[d]ifferences in experts' advice can often be resolved only on the basis of risk and value preferences." Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 Yale L.J. 219, 222 (1985). "This medical uncertainty accentuates the need for professional advice, but it also strengthens the case for ultimate decision by the person whose life is directly involved." *Id.*

[4] As noted by Judge Williams, the average cost of CAS services is about $286. 854 F.2d at 1395.

if the primary surgeon and the patient deem an assistant otherwise necessary to lessen the *general* risks of cataract surgery, *i.e.*, to deal with complications which arise not infrequently during such surgery on the elderly but which cannot specifically be predicted in advance or linked to any pre-existing complicating conditions. Petitioners do not challenge § 9307(a) of COBRA and do not dispute the government's right to so limit its own expenditures.

However, petitioners do challenge § 9307(c) of COBRA, which adds 42 U.S.C. §§ 1395u(k)(1) and (2). Section 9307(c) prohibits any physician from "receiving any payment directly from Medicare patients intended as recompense for a CAS' services," unless those services are otherwise reimbursable under the limited circumstances set forth in § 9307(a).[5] 854 F.2d at 1382. It thereby goes a giant step beyond the restrictions of § 9307(a) on government reimbursement for CAS services. Section 9307(c) prevents patients enrolled in Medicare from using *their own private funds* to pay for and obtain CAS services in order to lessen the general risks of cataract surgery. Unless a third party under contract to the government decides that an identifiable "complicating medical condition" already exists, a Medicare patient is precluded from privately selecting and paying for a lawful procedure that the patient, in consultation with a physician, has determined to be in his or her best medical interest.

While prohibiting patient payment for CAS services, § 9307(c) does not condemn or prohibit the performance of CAS services, however. Nor does it preclude payment by others than the patient for CAS services to the patient. Thus, a very few patients enrolled in Medicare may be able

[5] The penalty for any violation consists of sanctions of up to $2,000 per violation and expulsion from the Medicare program for up to five years. 42 U.S.C. § 1395u(j)(2); 42 U.S.C. § 1320a-7a.

to obtain CAS services to guard against general surgical risks. For example, those Medicare patients fortunate enough to have another third-party payor can obtain the desired CAS services by arranging for third-party payment. *See* Statement of the Department of Health and Human Services, Plaintiffs' Exhibit 2. Similarly, teaching hospitals, at which intern or resident services are routinely provided without cost to the patient, may provide an opportunity for a few others to obtain CAS services. Yet willing Medicare patients who desire and are able to afford CAS services, but who lack these indirect routes of payment, are precluded from purchasing those services directly. As the court of appeals concluded, "The expectation that more than a few patients will be able to avail themselves of these [other] options is unrealistic." 854 F.2d at 1384.

Finally, a Medicare patient can avoid § 9307(c) only by dropping out of Medicare Part B entirely. As the court of appeals pointed out, "The government acknowledges that because there is no such thing as service-specific partial enrollment in Medicare Part B, the patient can protect his physician from sanctions only by 'disenrolling' from Medicare. . . ." 854 F.2d at 1384. Thus, for example, a Medicare patient cannot avoid the impact of § 9307(c) by declining Medicare reimbursement with respect to all aspects of the cataract surgery, *e.g.*, the primary surgeon's bill. "[U]nless a patient relinquishes *all* Part B benefits by disenrolling from Medicare, he is not free to purchase this needed service." *Id.* (emphasis supplied). Consequently, as the majority opinion recognized, "most patients will be faced with the Hobson's choice of foregoing the desired service or relinquishing their Medicare benefits." *Id.*

**C. Proceedings In The District Court**

Petitioners include several Medicare patients who wish to reduce their risks during cataract surgery by retaining the

services of an assistant; their physicians, who believe that the use of an assistant during cataract surgery reduces patient risks; and two professional associations of ophthalmologists, suing on behalf of their members and their patients. They filed this lawsuit against the Secretary of the Department of Health and Human Services ("the government") seeking, *inter alia*, a declaratory judgment that § 9307(c) interferes with their constitutionally protected rights of liberty and privacy. Jurisdiction was based on 28 U.S.C. § 1331.

In their Complaint, petitioners alleged that "[n]umerous complications can occur in the course of cataract surgery which cannot be predicted in advance based on a complicating medical condition, or at all; except that statistically it is certain that such unpredictable complications will occur in some cases. Those complications create dangers of injury, including irreversible loss of sight." Complaint, ¶ 9. Petitioners also alleged that "[t]he risks of unpredictable complications that can occur in cataract surgery can be avoided or greatly reduced by the presence of a qualified assistant ophthalmologist." *Id.*, ¶ 10. They further specifically alleged that "an assistant ophthalmologist's attendance *is necessary* in cataract surgery to avoid or reduce physical injury." *Id.*, ¶ 12(c) (emphasis supplied).

The government moved to dismiss the complaint for lack of subject matter jurisdiction or, in the alternative, for failure to state a claim upon which relief can be granted. Following briefing on this motion, but prior to any ruling by the district court, petitioners moved for a preliminary injunction. On March 10, 1987, the district court issued an order denying the motion for a preliminary injunction. App., *infra*, 38a-39a. Characterizing § 9307 as a mere "withdrawal of federal funds," the district court held as a matter of law that such a withdrawal "does not interfere . . . with plaintiff patients' right to make decisions regarding their own health care." *Id.*

On March 12, 1987, the district court granted the government's motion to dismiss, apparently based on this same analysis. Its one-sentence March 12, 1987 order stated only that the dismissal was in "accordance with this Court's order of March 10, 1987. . . ." App., *infra*, 40a.

**D. Proceedings In The Court Of Appeals**

On August 19, 1988, a divided panel of the District of Columbia Circuit affirmed the dismissal of the case, albeit on grounds entirely different from those set forth by the district court. The court of appeals concluded that because § 9307(c) precludes Medicare patients from expending private funds for CAS services, "the regulatory scheme does impose a burden of significant magnitude on patients' medical choice" that "would not withstand scrutiny in the context of a recognized constitutional interest." 854 F.2d at 1384. The court concluded that "*if* the Constitution protects the right to make and implement the decision whether to procure the services of an assistant surgeon on a physician's advice, then § 9307(c) impermissibly infringes that right absent compelling justification." *Id.* at 1385 (emphasis supplied).

The majority held, however, that a patient's right to choose and procure a lawful medical treatment recommended by his or her physician does *not* constitute a cognizable liberty interest in most instances, and therefore is not entitled to any substantive constitutional weight. Instead, the majority held that only when a medical treatment is proved "indispensable to a patient's life, health or sight," so that its deprivation " 'shocks the conscience,' *Rochin* v. *California*, 342 U.S. 165, 172 (1952)," does patient decision-making regarding medical treatment rise to a level of constitutional significance. 854 F.2d at 1388. Applying this standard, the majority found petitioners' "liberty claims" not to be ripe

because of the difficulty in predicting whether those patients not receiving prior approval for CAS services will incur a magnitude of risk so severe as to make those services clearly "indispensable." As the majority stated:

> We are aware of appellants' allegation that every patient, regardless of pre-existing risk factors, is exposed to a significantly greater chance of unforeseen, dangerous complications without a second surgeon. It may be, however that only certain types of patients incur *the significant risk* without a second surgeon that constitutes *legally cognizable* injury.

*Id.* (emphasis supplied). In short, the majority's jurisdictional holding that petitioners' "liberty claims" are not ripe was based upon its substantive holding that only the deprivation of "indispensable" medical treatment raises "legally cognizable" constitutional concerns.

The majority did, however, decide the merits of what it characterized as petitioners' "privacy claims." *See* 854 F.2d at 1383. It held that the *only* medical choices entitled to constitutional privacy protection are those that are "indispensable to patient well-being," based upon "a definite showing of medical necessity and the unavailability of equally effective alternative therapy." 854 F.2d at 1391. This "privacy interest" standard is indistinguishable from the test adopted by the majority for recognizing "liberty interests" in the medical sphere.

Petitioners had, in any event, alleged the medical necessity of CAS services. See p. 8, *supra*. Yet even though the appeal before it was from the granting of a motion to dismiss, and petitioners' allegations were thus required to be treated as true, *Conley* v. *Gibson*, 355 U.S. 41, 45-46 (1957), the majority inexplicably applied a summary judgment standard of review. It found that petitioners had failed "on the record before us" to "create a genuine issue of material fact as to medical necessity," and concluded "that the dis-

trict court properly granted HHS' *motion to dismiss* this claim *on the basis of the evidence presented*." *Id.* at 1391-1392 (emphasis supplied).

Judge Williams concurred in part and dissented in part. Concluding that § 9307(c) might somehow be construed to enable patients to obtain CAS services through prepayment,[6] he concurred, although on wholly different grounds, in the majority's conclusion that certain of petitioners' claims were not ripe. 854 F.2d at 1393-94. Substantively, however, Judge Williams "emphatically" disagreed with the majority's attempt to define patient interests in medical decision-making solely in terms of medical necessity and without reference to "autonomy values." *Id.* at 1395-1396. Noting that "the value a person attaches to preservation of eyesight is highly subjective," Judge Williams stated that even if an attempt to "reduce the variability of possible outcomes" is not a " 'medical necessity,' . . . it is far from clear to me that the invasion of individual autonomy would be constitutional."[7] *Id.* at 1395.

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[6] Judge Williams suggested that patient prepayment to a physician for CAS services might be distinguished, for statutory purposes, from a patient payment made in response to a bill for CAS services received after the operation. 854 F.2d at 1393. Neither in the proceedings before the district court nor in those before the court of appeals, however, did the government itself endorse, much less advance, such a statutory interpretation. To the contrary, as the court of appeals majority noted, the claim that § 9307(c) bars *any* patient payment for CAS services is "without contradiction by HHS." 854 F.2d at 1382.

[7] Judge Williams also disagreed with the majority's creation of distinct "liberty" and "privacy" claims, and particularly with its characterization of the "privacy interests" asserted by petitioners: "The court characterizes the first [privacy] claim . . . as posing a 'facial' challenge to § 1395u(k), a pure legal issue independent of the . . . utility of the second surgeon. . . . My difficulty is that I do not believe plaintiffs have posed any such claim." 854 F.2d at 1394 (Williams, J.). In their suggestion for rehearing *en banc*, petition-

*(Footnote continued on next page)*

On December 2, 1988, petitioners' suggestion for a rehearing *en banc* was denied (App., *infra*, 36a), with Judge Williams separately concurring (App., *infra*, 37a).

## REASONS FOR GRANTING THE PETITION

Section 9307(c) of COBRA represents an unprecedented intrusion by government into the highly personal sphere of patient-physician medical decision-making. For the first time, the government is precluding patients from using their own funds to obtain lawful medical services recommended by their physicians as serving their best interests. Moreover, it is doing so even though these services undeniably involve no additional risk to the patient's health.

Indeed, the government has asserted no health protective rationale in support of § 9307(c). To the contrary, it has stated, "Defendant does not deny that the attendance of an assistant specialist may be *preferable* in *any* [cataract] operation, or that adverse medical consequences may otherwise result. . . ." Defendant's Opposition to Plaintiffs' Motion for Preliminary Injunction, p. 22 (emphasis supplied). Nonetheless, the government claims that "given the minute percentage of risk" (*id.*), these medically preferable CAS services are not worth their economic costs—even for Medicare patients who would prefer to minimize the incremental risk of loss of an eye or other serious injury by using their own money to pay for such services. Accordingly, the issue raised by this case is narrow: May the government effectively bar a patient from privately obtaining a potentially beneficial course of medical treatment that poses no health risks solely on the grounds that the economic cost of the proce-

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ers confirmed Judge Williams' understanding that their claim is not independent of the general utility of CAS services.

dure outweighs the government's valuation of the conceded potential medical benefits.[8]

The majority opinion of the court of appeals decided this question not by comparing the strength of the patient's interests against the strength of the interests asserted by the government, but by denying that any constitutionally protected patient interests exist at all — except in extreme medical circumstances. This holding is unprecedented, and conflicts with this Court's decisions regarding the scope of liberty and privacy interests. Moreover, the decision will have profound and far-reaching consequences, not only for the

[8] Petitioners of course recognize the legitimacy of government efforts to regulate and even ban a medical procedure in order to protect patient or community health, or in order to advance some other significant state interest. They do not, as the majority erroneously claimed, assert "a blanket right to obtain without any government interference every and any kind of treatment." 854 F.2d at 1390. Moreover, petitioners recognize that when such a significant regulatory justification has been invoked, substantial deference is due the underlying governmental determinations. But no such significant governmental interest is at issue here. As Judge Williams noted, "The *sole* interest asserted in favor of the restriction is the interest in preventing individuals from being harmed by making unwise expenditures of their own money; there is no claim that the presence of a second surgeon ever makes a cataract operation more risky. Thus, the state interest is not only paternalistic, but lies solely in protecting pocketbook interests of the supposed patient beneficiaries." 854 F.2d at 1395 (Williams, J.).

Judge Williams also correctly observed that plaintiffs do not "claim that they would have a constitutional claim if it were stipulated that a second surgeon contributed no increment in safety whatsoever in the unapproved situations." 854 F.2d at 1394 (Williams, J.). Methods of "treatment" which no reasonable person could believe to be efficacious, *i.e.*, quackery, are not entitled to constitutional protection. But CAS services, which are utilized at more than half of cataract surgeries in the United States (Declaration of Michael W. Jones, ¶ 11(b) ), and which the government itself has admitted are medically "preferable" (Defendant's Opposition to Plaintiff's Motion for Preliminary Injunction, p. 22), clearly do not fall into this category.

elderly seeking to protect their sight but also for all persons who seek to exercise choice regarding their medical treatment. By holding that the Constitution affords no protection to any patient treatment decisions other than those that are "indispensable to patient well-being" (854 F.2d at 1391) — not even to those involving procedures that may be medically preferable and lacking in countervailing risk — the court of appeals has gravely devalued historically protected patient rights. Accordingly, the decision of the court of appeals warrants further review, and reversal, by this Court.

**1. The Decision Below Conflicts With Decisions Of This Court.**

The court of appeals' rejection of patient liberty and privacy interests in medical decision-making conflicts with the decisions of this Court. "In the past this Court has noted that the right to personal security constitutes a 'historic liberty interest' protected substantively by the Due Process Clause." *Youngberg* v. *Romeo*, 457 U.S. 307, 315 (1982). Health is a traditionally recognized, fundamental element of personal security. *See, e.g.*, W. Blackstone, *Commentaries* 1:120-41 (1765), reprinted in *The Founder's Constitution* at 590-91 ("[T]he preservation of a man's health from such practices as may prejudice or annoy it . . . are rights to which every man is intitled [sic] . . ."). Consequently, the constitutional interest in personal security, whether denominated a liberty or privacy interest, includes an interest in controlling medical decisions potentially affecting one's health.

In determining the permissibility of government interference with a patient's decisions about his or her own medical treatment, this Court has consistently "weighed the individual's interest in liberty against the state's asserted reasons for restraining individual liberty." *Youngberg* v. *Romeo*, *supra*, 457 U.S. at 315. In no case has it held, or even sug-

gested, that an interest in medical decisions affecting one's health is not constitutionally protected at all.[9] Nor has this Court ever erected a threshold requirement that the medical procedure involved must be "indispensable," not merely advantageous, in order to merit constitutional consideration.

To the contrary, when government interference in medical decisions creates an increased risk to individual health, as petitioners allege here, this Court has held that "our society recognizes a significantly heightened privacy interest . . ." *Winston* v. *Lee*, 470 U.S. 753, 767 (1985). This is so even if the health risk is slight and uncertain.[10] In *Winston*, for example, the government sought to perform a surgical procedure to remove a bullet from a criminal defendant's body. Presented with conflicting evaluations of the risk of the surgery, the court of appeals concluded that "the statistical risk of actual physical harm . . . . is perhaps very low" and could

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[9] In *Whalen* v. *Roe*, 429 U.S. 589, 600 (1977), this Court ruled, under the particular facts before it, that the patients' interests in "the making of decisions about matters vital to the care of their health" were not sufficiently threatened to establish a constitutional violation. It did not hold that patient interests in medical decision-making are not a subject of constitutional protection.

[10] The majority opinion below erroneously claimed that this Court has declined to treat such matters as bodily invasion and medical treatment as implicating a "fundamental interest." 854 F.2d at 1391. In support, the majority cited *Schmerber* v. *California*, 384 U.S. 757 (1966) (upholding the Fourth Amendment reasonableness of a blood test), for the proposition that no "fundamental interest" is at stake here. But unlike this case, *Schmerber* did not involve a risk to health. That fact was central to the decision in *Schmerber*. *Id.* at 771. Yet even then, the interference in *Schmerber* was not deemed constitutionally insignificant. To the contrary, almost twenty years later the Supreme Court confirmed that "[t]he intrusion perhaps implicated Schmerber's most personal and deep-rooted expectations of privacy . . . ." *Winston* v. *Lee*, 470 U.S. 753, 760 (1985).

"be considered minimal." *Lee* v. *Winston*, 717 F.2d 888, 900 (4th Cir. 1983). Nonetheless, this Court reasoned:

> The operation sought will intrude substantially on respondent's protected interests. The medical risks of the operation, although apparently not extremely severe, are a subject of considerable dispute; *the very uncertainty militates against finding the operation to be "reasonable."*

*Winston, supra*, 470 U.S. at 766 (emphasis supplied). The Court held that, in the absence of compelling countervailing interests, the very possibility of even marginal medical risk precluded the endangering government action. *Id.*

This case is the obverse of *Winston*. In *Winston*, the government sought to *require* a medical procedure that could pose risks to the patient — without any countervailing compelling justification. Here, the government seeks to *forbid* access to a medical procedure that can avoid risk to the patient — again without any countervailing compelling justification. *Cf. Memorial Hospital* v. *Maricopa County*, 415 U.S. 250, 263 (1974) (holding that "conservation of the taxpayers' purse" is not a sufficient justification for burdening fundamental rights). The infringement on protected patient interests is the same. The only real difference is that here the government interest is not only not compelling, it is virtually nonexistent. It is difficult to perceive any legitimate government interest in preventing a patient from spending his or her own funds to lessen personal health risks.

The decision in *Thornburgh* v. *American College of Obstetricians and Gynecologists*, 476 U.S. 747 (1986), reinforces these conclusions. In *Thornburgh*, this Court considered a state statute that regulated the medical techniques used in post-viability abortions. The statute required use of a technique maximizing the chances of fetal survival unless,

in the physician's good-faith judgment, that technique "would present a significantly greater medical risk to the life or health of the pregnant woman." *Id.* at 768. The statute could therefore result in the pregnant woman being exposed to some minimally enhanced medical risk, as long as the risk to the woman was not "significantly greater" than that presented by alternative abortion techniques. This Court invalidated the statute. It held that *any* "trade-off" requiring the woman to bear an increased medical risk in order to save her viable fetus is constitutionally unacceptable. *Id.* at 768-69. *See also Colautti* v. *Franklin*, 439 U.S. 379, 397-401 (1979).

Contrary to the majority below, this portion of *Thornburgh* cannot be interpreted as protecting medical decision-making "as a means to the end of free reproductive self-determination or autonomy." 854 F.2d at 1389. The statute at issue in *Thornburgh* dealt with *post*-viability abortions. At this stage, the woman's interest in "free reproductive self-determination" is considered subordinate to the state's interest in protecting fetal life. *Roe* v. *Wade*, 410 U.S. 113, 163-64 (1973). Consequently, the constitutional protection afforded post-viability abortion decisions is based on the woman's interest in preserving her own health, not on any claim of reproductive freedom.[11] *See Harris* v. *McRae*,

[11] The court of appeals majority sought to sweepingly distinguish all precedents protecting medical decision-making in the abortion context as follows: "The Constitution shelters the medical decision-making process in the context of abortion not because it is 'medical' but as a means to the end of free reproductive self-determination or autonomy." 854 F.2d at 1389. For the reasons already discussed above, this interpretation is clearly mistaken with respect to post-viability abortions. Moreover, this Court has frequently emphasized that the protections generally afforded the abortion decision rest primarily on the medical nature and implications of that decision. *See, e.g., Roe* v. *Wade*, 410 U.S. 113, 165-166 (1973) ("the abortion decision in all its aspects is inherently, and *(Footnote continued on next page)*

448 U.S. 297, 316 (1980). The "paramount" nature of this health interest, *Thornburgh*, *supra*, 476 U.S. at 769, overcomes even the state's compelling interest in fetal survival. *Id.*; *Roe* v. *Wade*, *supra*. *A fortiori*, when, as with § 9307(c), the government's only interest in subjecting a patient to an enhanced health risk is economic, and the relevant economic interest is that of the patient and not the government, such action is clearly constitutionally unjustifiable.[12]

*Winston* and *Thornburgh* reflect an engrained understanding, deeply rooted throughout our jurisprudence, that patients have an important interest in determining the level of risk they are willing to accept in the course of medical treatment.[13] This understanding likewise permeates the nu-

primarily, a medical decision"); *Harris* v. *McRae*, 448 U.S. 297, 316 (1980) ("It is evident that a woman's interest in protecting her health was an important theme in *Wade* . . . [I]t could be argued that the freedom of a woman to decide whether to terminate her pregnancy for health reasons does in fact lie at the core of the constitutional liberty identified in *Wade*").

[12] Similarly, it is the minimal nature of the government interest claimed to support § 9307(c) that is the basis of petitioners' constitutional objection to the approval process—not some assertion by petitioners of an absolute right to be free from "*any* statute requiring third party permission to procure a course of medical treatment." 854 F.2d at 1383 (emphasis supplied). Far more substantial state interests have been held insufficient to justify parallel restrictions on a patient's "right to receive medical care in accordance with her licensed physician's best judgment. . . ." *Doe* v. *Bolton*, 410 U.S. 179, 197 (1973) (invalidating statute that required hospital committee approval and concurrence of two physicians other than the patient's personal physician before medical procedure could be performed).

[13] Recognition of the importance of the patient's interest in determining his or her own medical treatment underlies the common law doctrine of informed consent, for example. "The root premise is the concept, fundamental in American jurisprudence, that '[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body . . . .'" *Canterbury* v. *Spence*, 464 F.2d 772, 780 (D.C. Cir.), *cert. denied*, 409 U.S. 1064

*(Footnote continued on next page)*

merous other cases which, as the majority below acknowledged, "aris[e] in disparate legal circumstances . . . [and] speak to a zone of privacy in the patient physician-relationship," but which the majority mistakenly dismissed as "not present[ing] a coherent body of law." 854 F.2d at 1390. *See, e.g., Doe* v. *Bolton*, 410 U.S. 179, 219-220 (1973) (Douglas, J., concurring) (the right of privacy includes "the right to care for one's health and person" and "has no more conspicuous place than in the physician-patient relationship"); *England* v. *Louisiana State Bd. of Medical Examiners*, 259 F.2d 626, 627 (5th Cir. 1958) ("the state cannot deny to any individual the right to exercise a reasonable choice in the method of treatment of his ills"), *cert. denied*, 359 U.S. 1012 (1959); *Gray* v. *Romeo*, 697 F. Supp. 580, 584-86 (D.R.I. 1988) (finding constitutional right "to control medical decisions affecting one's body," subject to important state interests); *Andrews* v. *Ballard*, 498 F. Supp. 1038, 1047-48 (S.D. Tex. 1980) ("[t]he decision to obtain or reject medical treatment . . . is both personal and important enough to be encompassed by the right of privacy"); *Hawaii Psychiatric Soc'y, Dist. Branch of American Psychiatric Ass'n* v. *Aryoshi*, 481 F. Supp. 1028, 1038 (D. Haw. 1979) ("decisions regarding medical care also fall within this protected zone of autonomy").

To be sure, the existence of a protected interest in medical decision-making affecting bodily security does not mean that this patient interest cannot be overridden by significant government interests. *Cf.* p. 13, n.8, *supra.* Government can,

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(1972) (quoting *Schloendorff* v. *Society of New York Hospital*, 211 N.Y. 125, 129, 105 N.E. 92, 93 (1914) (Cardozo, J.) ). *Accord Union Pacific Ry. Co.* v. *Botsford*, 141 U.S. 250, 251 (1891); *Natanson* v. *Kline*, 186 Kan. 393, 410, 350 P.2d 1093, 1106 (1960). *See also* F. Harper and F. James, *The Law of Torts* § 17.1 (2d ed. 1986); President's Commission for the Study of Ethical Problems in Medicare and Biomedical and Behavioral Research, *Summing Up*, p. 67 (1983).

for example, require an individual to submit to a medical procedure which poses some risks in order to ensure preservation of the health of the community as a whole. *See Jacobson* v. *Massachusetts*, 197 U.S. 11, 26 (1905) (recognizing that compulsory vaccination infringes on liberty interests but holding that "the common good" outweighs these individual interests), cited by the court of appeals majority, 854 F.2d at 1391. *Cf. Thornburgh* v. *American College of Obstetricians and Gynecologists, supra*, 476 U.S. at 809 (White, J., dissenting) (recognizing that "a compelling state interest may justify the imposition of some physical danger upon an individual"). These cases do not support the notion, however, that no constitutionally cognizable patient interest exists in the first place, thereby obviating the need for any weighing of interests. Rather, they stand only for the proposition that individual interests in ensuring bodily security can be overridden by significant countervailing government interests.

The court of appeals majority seems to have confused the question of the existence of a constitutionally protected interest with the question of whether that interest can be immunized from all government regulation.[14] But the fact that patient interests in medical decision-making can be overridden in some circumstances does not mean that they are not constitutionally protected at all. No decision of this Court supports the extraordinarily restrictive approach of the appellate majority. Review by this Court is therefore necessary to confirm that patients possess a constitutional interest in choosing a potentially safer course of medical treatment, even if that treatment is not "indispensable," and that

[14] In fact, the base-line test created by the court of appeals for identifying constitutionally cognizable patient interests, *i.e.*, "indispensable" medical treatment, is arguably a standard for identifying patient interests that cannot be overridden even by compelling state interests.

the strength of the government's reasons for restricting this patient interest is of relevance and must be weighed.

**2. This Case And The Issues That It Presents Are Of National Importance.**

Section 9307(c) directly affects millions of senior citizens who require cataract surgery, almost all of whom are enrolled in Medicare Part B. *See* 854 F.2d at 1381 (estimating that "one million cataract removals are performed annually"). As the court of appeals recognized, most of these patients' requests for approval of CAS services will inevitably be denied because the carriers and peer review organizations under contract to the government are statutorily forbidden from authorizing CAS services in the absence of a pre-existing "complicating medical condition." 854 F.2d at 1387, 1393. Medicare patients are thereby effectively deprived of the ability to take measures to increase the safety of cataract surgery. They are deprived of the ability to judge for themselves, after being fully informed of all factors, whether the incremental risk of loss of an eye or other serious injury is worth additional precautions and expenditures.

The decision below also has profound ramifications extending beyond the safety of cataract operations. Whether a patient has a constitutionally cognizable interest in medical decisions potentially affecting his or her health is an issue of fundamental and recurring importance for all individuals who may be affected by illness, disease or disability.[15] Yet

[15] "It is the individual making the decision, and no one else, who lives with the pain and disease. It is the individual making the decision, and no one else, who must undergo or forego the treatment. And it is the individual making the decision, and no one else, who if he or she survives, must live with the results of that decision. One's health is a uniquely personal possession. . . . The importance of decisions affecting it cannot be overstated."

*Andrews* v. *Ballard, supra*, 498 F. Supp. at, 1047

by restricting constitutional protection only to those treatment decisions that can be proved "indispensable," the court of appeals has eliminated patient participation interests across a broad range of medical decisions that vitally affect health.[16] "Even the most mundane case . . . may well have no objective medical criteria that specify a single best way to achieve the goal." 1 President's Commission for the Study of Ethical Problems in Medicare and Biomedical and Behavioral Research, *Making Health Care Decisions* 42 (1982). In holding that patient interests in cases of this sort do not count at all, the court of appeals has effectively eliminated any check on governmental intrusion into medical decision-making in most instances.

Finally, the significance of the issue here is underscored by the fact that the Court has noted jurisdiction in a case that raises related issues—*Webster* v. *Reproductive Health Services*, No. 88-605, *prob. juris. noted*, 57 U.S.L.W. 3441 (1989).[17] Regardless of how this Court may resolve *Webster*, however, this case is independently worthy of review. The

[16] Indeed, the court of appeals has restricted the liberty interests of the free populace to the minimum level of care *required* to be provided *by the government* to incarcerated criminals. *See, e.g., Estelle* v. *Gamble*, 429 U.S. 97, 103 (1976); *Bowring* v. *Godwin*, 551 F.2d 44, 47-48 (4th Cir. 1977) (Eighth Amendment's prohibition on "cruel and unusual punishment" requires the government to provide only "medically necessary" treatment).

[17] In *Webster*, the question of constitutional protection for medical decision-making is posed, albeit in a very different context. This Court has agreed to consider, *inter alia*, whether certain state-mandated medical tests and restrictions on the provision of medical counseling in connection with abortions are violative of constitutional rights. 57 U.S.L.W. 3441 (1989). Determining whether or not protection of medical decision-making is the basis, or part of the basis, of the privacy interests at issue in *Webster* may be particularly significant in determining how the balance of interests should be struck as between the state and the individual. *See also* p. 17, n.11, *supra*.

*(Footnote continued on next page)*

immediate effect of the court of appeals' decision on the millions of the elderly who require cataract surgery alone justifies review by this Court. Review is still more essential, however, to prevent the generalized *carte blanche* right of governmental intrusion into medical decision-making authorized by the court of appeals. Nothing less than the integrity of fundamental principles of individual self-determination in making reasonable choices about health is at stake.

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*(Footnote continued from previous page)*

*Webster* is considerably more complicated than the present case, however. Among the issues in *Webster* are whether the Missouri statutory provisions legally impair protected privacy rights and, if so, whether such impairment is justified by a compelling state interest. In the present case there is no claim of a compelling government interest. Moreover, the court of appeals here has already determined that to the extent that patients have a constitutionally cognizable interest in making and implementing the decision to procure CAS services, § 9307(c) impermissibly infringes upon that interest. 854 F.2d at 1384-85.

## CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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March 2, 1989

# APPENDICES

## APPENDIX A

**NEW YORK STATE OPHTHALMOLOGICAL SOCIETY, et al., Appellants,**

**v.**

**Otis R. BOWEN, Secretary, Health and Human Services.**

**Nos. 87-5057 and 87-5065.**

United States Court of Appeals, District of Columbia Circuit.

Argued Nov. 19, 1987.
Decided Aug. 19, 1988.

Appeal from the United States District Court for the District of Columbia.

William A. Dobrovir, with whom Robert L. Baum, Washington, D.C., was on the brief, for appellants.

Peter R. Maier, Atty., Dept. of Justice, with whom Richard K. Willard, Asst. Atty. Gen., Joseph E. diGenova, U.S. Atty., and John F. Cordes, Atty., Dept. of Justice, Washington, D.C., were on the brief, for appellee. Joel E. Momkin, Atty., Dept. of Justice, Washington, D.C., also entered an appearance for appellee.

Mark B. Rotenberg was on the brief for amicus curiae, American Academy of Ophthalmology, Inc., urging reversal.

Jack R. Bierig, Chicago, Ill., was on the brief for amicus curiae, American Medical Ass'n, urging reversal.

Before MIKVA and WILLIAMS, Circuit Judges, and GORDON,* Senior District Judge.

Opinion for the Court filed by Circuit Judge MIKVA.

Concurring Opinion filed by Circuit Judge STEPHEN F. WILLIAMS.

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*Sitting by designation pursuant to 28 U.S.C. § 294(d).

MIKVA, Circuit Judge:

This is a consolidated appeal from a district court judgment for appellee, the Secretary of the Department of Health and Human Services ("HHS"), in a class action brought by individual ophthalmologists, their patients, and two professional associations in New York and California suing on behalf of all ophthalmologists and cataract patients in those states ("appellants"). Appellants challenge the constitutionality of § 9307(c) of the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), which adds subsections (k)(1) and (2) to § 1842 of the Social Security Act, 42 U.S.C. § 1395u. These amendments prohibit physicians from billing individuals enrolled in Medicare Part B for services of an assistant cataract surgeon ("CAS") unless those services have been approved by an insurance carrier or designated state Peer Review Organization ("PRO").

The district court denied appellants' motion for a preliminary injunction and granted HHS' motion to dismiss. Appellants seek a permanent injunction to restrain enforcement of these amendments and a declaratory judgment that these provisions interfere with patients' and physicians' constitutional rights. On review, we reject appellants' contention that the statute facially violates patients' and physicians' constitutional right to privacy, and affirm the district court's grant of HHS' motion to dismiss with respect to this challenge. We dismiss appellants' remaining constitutional claims as not presently ripe for review.

## I. Background

Cataract surgery involves the removal of a clouded lens from the eye and its replacement with a prosthetic lens. An estimated one million cataract removals are performed annually, most on elderly patients enrolled in Medicare. Consequently, reimbursement for cataract surgery constitutes a

substantial expense to the Medicare Part B Program, which reimburses for physicians' services. According to a 1985 audit report conducted by the HHS Inspector General, 1983 expenditures for ophthalmology services by surgeons and assistant surgeons in cataract operations amounted to $822 million and $42 million respectively. About 90 percent of Medicare reimbursement costs for eye surgery were related to cataract surgery. *See* Office of Inspector General, Office of Audit, Department of Health and Human Services, *Review of Medicare Payments for Assistant Surgeon Services During Cataract Surgery* 6 (1985) ("Report"), Joint Appendix ("J.A.") at 43.

In an effort to reduce these costs, the Inspector General reviewed the Medicare reimbursement policies for these services and investigated the use of cataract assistant surgeons nationwide. Before 1987, Medicare reimbursed patients for the use of an assistant surgeon if such use was the "generally accepted procedure among ophthalmologists in the local community." Report at 5, J.A. at 42. The determination of allowability of these services was the responsibility of the carrier in each state, based on the "prevailing practice that exists in that locality." *Id.* The Medicare regulations "[did] not comment upon the issue of the medical necessity for assistant surgeons for these services." *Id.* In his review of cataract surgery in 29 states, the Inspector General found that carriers acting for HHS in at least nine states restricted reimbursement for the services of assistant surgeons in cataract operations. The Report disclosed that the states with "lower ratios of paid assistant surgeon services *** were states that also had restrictions regarding *** payment." *Id.* at 6, J.A. at 43. In those locales, trained technicians, resident physicians, and paramedical personnel provided assistance at surgery. Ophthalmologists from those states generally agreed with the carriers that two physicians were unnecessary.

The Inspector General did not cite data demonstrating the relative complication rates or comparative safety of the use of personnel with different levels of training as assistants. The Report nevertheless concluded that

> in view of the numerous cataract surgeries successfully performed nationwide without the use of assistant surgeons * * * the payment of an assistant surgeon for routine cataract surgery results is unnecessary and ineffective use of Medicare program funds. Individual surgeons' preferences with respect to the use of assistant surgeons notwithstanding, other qualified medical personnel are normally available and routinely used during surgery.

*Id.* at 10, J.A. at 47. The Report recommended that the Health Care Financing Administration ("HCFA") promulgate a national policy for eliminating Medicare coverage for second surgeons in routine cataract operations. It also suggested that HCFA establish a mechanism of prior approval for those cases in which the use of a second surgeon is medically indicated.

Influenced by this report, Congress in 1986 amended the legislation governing the Medicare funding program to regulate the use of assistant surgeons for cataract operations by adding sections 1395y(a)(15) and 1395u(k) to Title 42. Section 1395y(a)(15) provides that Medicare will only reimburse for the services of a CAS if a designated state PRO finds that the patient has a "complicating medical condition." The PROs are charged with the responsibility of formulating procedures to determine which patients shall be approved. *See* 42 U.S.C. § 1320c-3(a)(8). Sections 1395u(k)(1) and (2) provide that any physician who "knowingly and willfully" bills patients enrolled in Medicare Part B for services of an assistant at cataract surgery without prior PRO approval will incur civil sanctions as provided in § 1395u(j)(2), including a fine or disqualification for up to 5 years from participation

as a Medicare Part B provider. Congress' decision to penalize physicians charging patients for second surgeons was motivated by the concern that Medicare beneficiaries would be forced to bear the cost of the services that Medicare would no longer reimburse. *See* H.R. Rep. No. 241, 99th Cong., 2d Sess. 42 (1986), U.S.Code Cong. & Admin. News 1986, pp. 42, 620 (bill authorizes sanctions to "ensure that beneficiaries are protected from additional out-of-pocket costs"); *see also* 131 Cong.Rec. 29,831 (1985) (remarks of Rep. Waxman) (describing a bill to "reduce Medicare and Medicaid outlays without harming program beneficiaries").

Enforcement of these amendments was temporarily delayed at the request of Congress to allow the PROs and insurance carriers the opportunity to set up pre-approval programs in accordance with HCFA guidelines. In January 1987, HCFA formulated pre-procedure review guidelines that were to apply to operations performed after March 1, 1987. Designated PROs in both New York and California established criteria for granting approval for assistant surgeons based on "complicating medical conditions."

Appellants sued in district court for a preliminary injunction to prevent the agency from putting the penalty provisions into effect. Appellants' objection was confined to sections 1395u(k)(1) and (2), which they interpreted—without contradiction by HHS—as prohibiting the physician from receiving any payment directly from Medicare patients intended as recompense for a CAS' services. Appellants did not challenge the reimbursement disallowance provision, § 1395y(a)(15). The complaint was framed as a class action, although the class was not certified by the district court prior to granting HHS' motion to dismiss. The district court denied the motion for preliminary injunction and rejected appellants' contention that the statutory scheme violated patients' and physicians' constitutional rights. The court stated

that § 9307(c) "does not interfere with plaintiff physicians' right to practice their profession or with plaintiff patients' rights to make decisions regarding their own health care." District Court Order, Mar. 10, 1987, at 1 (citation omitted). The court found the statute rationally related to the legitimate government purpose of "the prohibition of the expenditure of federal funds determined to be medically unnecessary while protecting medicare beneficiaries." *Id.* at 2. The court granted HHS' motion to dismiss and ordered that § 9307 go into effect as scheduled.

## II. Appellants' Arguments on Appeal

In their appeal to this court, appellants argue that the statutory scheme penalizing physicians for charging patients enrolled in Medicare for CAS services violates patients' and physicians' constitutional rights of privacy, due process, and association. They assert that the challenged amendments enforce an unconstitutional interference in patient privacy, independence, and autonomy by imposing a penalty on the choice to lessen the dangers of surgery by arranging for and paying an assistant surgeon.

Appellants advance the comprehensive thesis that medical decisions are "core" private decisions. A fundamental tenet of privacy jurisprudence, as it has been applied to other types of personal matters, is that the individual most directly concerned is entitled to make and implement the protected decision autonomously and free from paternalistic government intrusion. *See, e.g., Zablocki v. Redhail,* 434 U.S. 374, 98 S.Ct. 673, 54 L.Ed.2d 618 (1978) (decision to marry); *Moore v. East Cleveland,* 431 U.S. 494, 97 S.Ct. 1932, 52 L.Ed.2d 531 (1977) (decision to live with extended family members); *Griswold v. Connecticut,* 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed.2d 510 (1965) (reproductive choice). Appellants argue that the constitutional right to privacy also protects autonomy in making medical decisions.

As an element of this right—as well as of the right of free association—appellants claim that the patient is entitled to decide who shall be involved in determining the care he receives. They claim that a statute forcing the patient to "run the gauntlet" of application for PRO approval violates the right of the patient to determine for himself, or with the advice of his chosen physician, how he shall be treated. Such interference can be justified only by a compelling government interest in protecting life or health. Thus, appellants request relief from the obligation to submit their treatment plan for approval.

In addition, appellants maintain that the right to privacy protects patients' interest in *procuring* the treatment of choice. As an aspect of appellants' asserted privacy interest, this right to obtain treatment does not appear to depend on any proof of the "medical necessity" of the desired service. Although appellants maintain that surgeon-assisted surgery is measurably safer and thus medically necessary to the preservation of sight, they insist that *all* medical treatment decisions are protected from state interference because they are inherently private and peculiarly "personal."

We thus interpret appellants' privacy argument as a facial attack applicable against any statute requiring third-party permission to procure a course of medical treatment—including surgeon-assisted cataract surgery. This theory focuses on the decision-making process as well as access to treatment. Appellants also assert a liberty interest in the procurement of medical treatment necessary to vindicate bodily security. As we read the case law on constitutional liberty and substantive due process, any compromise of a patient's liberty interest must turn on deprivation of treatment *essential* to health and life. Thus, the liberty claim focuses solely on patients' entitlement to a result—access to

vital medicine treatment—apart from whether that result can only be obtained with governmental approval.

As we discuss more fully below, to the extent that appellants launch a facial challenge to the amendments mandating PRO interference in a medical determination, their claim sounds in privacy. To the extent they object to denial of access, we think they allege violations of both due process, or "liberty," rights as well as the right to privacy. Our analysis of ripeness, standing, and the merits of appellants' position takes this distinction as its starting point.

## III. Unconstitutional Interference

We are met at the outset by HHS' claim that any individual patient can entirely avoid the application requirement or procure desired treatment despite PRO disapproval by obtaining an assistant surgeon through some method other than the normal one of paying him a fee for his services. For example, HHS suggests that the patient may find a CAS who will participate for free, who will enter into a fee-splitting arrangement with the principal surgeon, or who will provide uncompensated assistance in exchange for his colleague's assistance at a future operation. The patient may seek treatment at a teaching hospital in which an intern or resident assists at cataract surgery at no extra cost. Alternatively, the patient can "choose" to forego Medicare Part B participation altogether, thus putting his physician beyond the reach of the provisions. The government acknowledges that, because there is no such thing as service-specific partial enrollment in Medicare Part B, the patient can protect his physician from sanctions only by "disenrolling" from Medicare.

Whether patients can put themselves beyond the reach of these amendments by availing themselves of the alterna-

tives outlined by HHS presents a threshold question: whether Medicare's regulation of CAS services threatens to injure the rights that appellants claim are constitutionally protected. We find that the regulatory scheme does impose a burden of significant magnitude on patients' medical choice. A straightforward reading of the statutory language indicates that a patient enrolled in Medicare Part B may not pay for the services of a physician as assistant at his surgery without subjecting his doctor to sanctions. Even a physician who does not participate in Medicare and accept Medicare reimbursement may incur a monetary penalty by billing a Medicare-enrolled patient. Thus, unless a patient relinquishes all Part B benefits by disenrolling from Medicare, he is not free to purchase this needed service. We do not agree that the options the government enumerates mitigate the burden imposed by § 9307(c) on a patient's decision regarding his choice of treatment. The expectation that more than a few patients will be able to avail themselves of these options is unrealistic. As a practical matter, most patients will be faced with the Hobson's choice of foregoing the desired service or relinquishing their Medicare benefits.

Moreover, the type of burden imposed on patients by this scheme, although indirect, would not withstand scrutiny in the context of a recognized constitutional interest. In cases upholding a ban on federal funding of abortion services, the Supreme Court drew an important distinction between upholding a subsidy and imposing a penalty. The Court recognized, as the appellants here acknowledge, that mere "refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity," *Harris v. McRae*, 448 U.S. 297, 317 n. 19, 100 S.Ct. 2671, 2688 n. 19, 65 L.Ed.2d 784 (1979), because the state is not obligated to remove obstacles "not of its own creation" to the exercise of constitutional rights. *Id.* at 316, 100 S.Ct. at 2688; *see also Maher v. Roe*, 432 U.S. 464, 474-75, 97 S.Ct. 2376, 2383, 53

L.Ed.2d 484 (1976). A provision, however, that subjects those who engage in protected activity to an unrelated or collateral sanction—such as deprivation of benefits to which an individual is otherwise entitled—significantly burdens the exercise of rights. As the Court stated in *McRae*, "[a] substantial constitutional question would arise if Congress had attempted to withhold all Medicaid benefits from an otherwise eligible candidate simply because that candidate had exercised her constitutionally protected freedom to terminate her pregnancy by abortion." 448 U.S. at 317 n. 19, 100 S.Ct. at 2688 n. 19; *see also Maher v. Roe*, 432 U.S. at 474 n. 8, 97 S.Ct. at 2383 n. 8 (citing *Shapiro v. Thompson*, 394 U.S. 618, 89 S.Ct. 1322, L.Ed.2d 600 (1969) (denial of welfare to those exercising right to travel is analogous to criminal fine and justifies strict scrutiny) and *Memorial Hospital v. Maricopa County*, 415 U.S. 250, 97 S.Ct. 1076, 39 L.Ed.2d 306 (1974) (same)). *See generally* Kreimer, *Allocational Sanctions: The Problem of Negative Rights in a Positive State*, 132 U.Pa.L.Rev. 1293, 1343-47 (1984).

We doubt that a statute requiring an abortion patient to relinquish medical benefits if she is unable to find a physician willing either to work for free or to incur sanctions would pass constitutional muster. By analogy, a provision that, as a practical matter, conditions access to a desired service or exemption from an approval requirement on a patient's "voluntary" decision to give up a valuable benefit is tantamount to a direct penalty imposed on the patient who chooses the service. In sum, if the Constitution protects the right to make and implement the decision whether to procure the services of an assistant surgeon on a physician's advice, then § 9307(c) impermissibly infringes that right absent compelling justification.

Having decided that the statutory scheme at issue significantly impedes appellants' freedom of choice, we must de-

cide whether the choices regulated by § 9307(c) enjoy constitutional protection. Before proceeding with this inquiry, we address HHS' standing and ripeness arguments. Although we find that appellants have standing to mount a pre-enforcement privacy challenge to § 9307(c) and that this challenge is ripe for review, we hold that failure to exhaust administrative procedures makes their "liberty" claim unripe.

## IV. Preliminary Issues

### A. *Standing*

HHS argues that because no appellant has sought or been denied PRO approval for a second surgeon, neither the patients nor the ophthalmologists have standing to bring this claim. HHS maintains that appellants are unable to demonstrate actual or threatened injury until their applications have received adverse action, because § 9307(c) does not deprive these individuals of any right or liberty if a PRO approves their Medicare reimbursement request. Because physicians' claims of injury derive from those of their patients, physician appellants also cannot claim injury to their due process or associational rights until patients sustain injury.

We disagree that appellant patients, and by extension their physicians, lack standing to pursue this challenge in its current posture. First, we do not agree that appellants' injury on all theories advanced by them accrues only when the sanctions imposed by § 9307(c) come into play—that is, after PRO disapproval. Appellants claim that the third-party approval requirement itself invades their privacy interest. Where there is "a legal right, the requisite injury for standing would be found in an invasion of that right." *Schlesinger v. Reservists Comm. to Stop the War*, 418 U.S. 208, 224 n. 14, 94 S.Ct. 2925, 2934 n. 14, 41 L.Ed.2d 706 (1974) (citations omitted). Because no patient in the proposed class of those

planning or needing cataract surgery is exempt from the approval requirement, all face imminent constitutional injury if forced to submit to the statutorily mandated procedure.

With respect to any constitutional interests of patients and physicians that are not detrimentally affected until the CAS applications are actually *denied*—such as certain "liberty" interests—it is less clear whether plaintiffs as the class of *all* patients planning cataract surgery have standing to sue, or whether it can now be predicted with certainty that the named representatives " 'possess the same interest and suffer the same injury' as the class members." *East Texas Motor Freight Sys. v. Rodriguez*, 431 U.S. 395, 403, 97 S.Ct. 1891, 1896, 52 L.Ed.2d 453 (1977) (quoting *Schlesinger v. Reservists Comm. to Stop the War*, 418 U.S. 208, 216, 94 S.Ct. 2925, 2929, 41 L.Ed.2d 706 (1974)). We need not resolve these aspects of the standing question, however, because we hold that the liberty, or due process, claim that accrues solely upon denial of approval is not ripe for judicial review at the pre-enforcement stage.

B. *Ripeness*

HHS insists that until appellants have exhausted administrative procedures by submitting CAS requests for PRO approval, this controversy is not ripe for judicial review. HHS analyzes ripeness according to the two-part test of (1) fitness of the issues for judicial determination and (2) hardship to the parties of withholding judicial consideration. *See Abbott Laboratories v. Gardner*, 387 U.S. 136, 149, 87 S.Ct. 1507, 1516, 18 L.Ed.2d 681 (1967). With respect to the first prong, HHS asserts that review is premature because factual development may aid this court's review, and pre-enforcement judicial review may undermine the integrity of a centralized scheme for administrative review like the one HHS has established for assistant surgeon approval. The agency also points out that exhaustion of PRO procedures may moot

many patients' complaints because these patients may be approved. HHS disagrees that postponement of review will cause patients irreparable injury, because appellants face no choice between compliance or defiance until HHS has issued a final action refusing to give approval.

In order to address adequately the preliminary issue of ripeness, we must reiterate the distinction between appellants' privacy arguments and the liberty violation thesis because ripeness analysis reveals important differences in readiness for judicial review between these grounds for challenge. The injuries of which appellants complain under their privacy and liberty theories accrue at different points of the administrative process mandated by the challenged statutory provisions. Appellants allege that operation of the statute at all stages of the administrative process infringes patients' privacy rights of autonomous decision-making. This facial privacy challenge encompasses not only the patients' claims of violation of rights of privacy and association, but also the physicians' claims on these grounds, which are entirely derivative from the patients'. *See Whalen v. Roe,* 429 U.S. 589, 604 n. 33, 97 S.Ct. 869, 879 n. 33, 51 L.Ed.2d 64 (1977). PRO *disapproval* undermines patients' liberty or "due process" interests in bodily security. This claim depends on actual denial of patients' access to needed treatment. These observations are key to our discussion of the ripeness of appellants' constitutional claims.

1. *Ripeness of privacy and association claims*

HHS contests the fitness for review of appellants' complaint under the first prong of *Abbott Laboratories* by addressing factors at the intersection of ripeness and exhaustion. The ripeness doctrine focuses on the pragmatic question of the competence of the courts to resolve disputes without further administrative refinement of the issue. *See* 13A C. Wright, A. Miller & E. Cooper, *Federal Practice and*

Procedure § 3532 (2d ed. 1984). A controversy is ripe if further administrative process will not aid in the development of facts needed by the court to decide the question it is asked to consider.

Insofar as appellants facially attack the comprehensive approval scheme on privacy grounds, we disagree with HHS' argument that further administrative process will develop the controversy to aid this court's review. The privacy challenge appellants present to the court is a purely legal challenge to a statutory approval requirement *per se*. Further facts will not help the court decide whether the right to privacy protects patients from the requirement to seek permission to go forward with their medical plans. We fail to see what will be learned by waiting until the "agency action or policy in question has assumed either a final or more concrete form." *Better Government Ass'n v. Department of State*, 780 F.2d 86, 92 (D.C. Cir.1986). How the PROs apply the guidelines concerning "complicating medical conditions" or other factors that entitle patients to approval does not bear on whether the PROs should be making this inquiry in the first place. "Because this appeal raises a facial attack on the constitutionality of [a statutory provision]*** we will never be in better position to decide the issue." *Whitney v. Heckler*, 780 F.2d 963, 969 n. 6 (11th Cir.) (citations omitted), *cert. denied*, 479 U.S. 813, 107 S.Ct. 65, 93 L.Ed.2d 23 (1986).

The fact that the privacy objection also addresses itself to injury peculiar to those patients who in fact are denied PRO approval does not undermine this claim's ripeness. Even if only a subset of patients may claim a privacy interest in the decision whether to engage a CAS—e.g., because undergoing an operation performed by one surgeon puts them at special risk and makes their decision particularly "important"—those patients can assert a privacy interest in avoiding the approval requirement at its inception, as well as in

obtaining the service. Therefore, the court need not wait to see if these patients are denied approval to determine whether the statute infringes their privacy right. The statutory scheme as a whole clearly applies to them. The court need only determine if the statute implicates a privacy interest for some or all patients covered by it.

The doctrine of exhaustion, however, introduces other considerations bearing on their claim's "fitness" for review. The exhaustion requirement stresses both respect for agency prerogatives and principles of judicial economy by seeking to prevent "premature interruption of the administrative process." *McKart v. United States*, 395 U.S. 185, 193, 89 S.Ct. 1657, 1662, 23 L.Ed.2d 194 (1968). The requirement prevents the "frequent and deliberate flouting of administrative process [that] could weaken the effectiveness of an agency," *id.* at 195, 89 S.Ct. at 1663, and preserves agency autonomy by allowing it to "exercise its discretion or apply its expertise," *id.* at 194, 89 S.Ct. at 1663. Requiring exhaustion also promotes judicial efficiency by "avoiding needless repetition of administrative and judicial factfinding," *Andrade v. Lauer*, 729 F.2d 1475, 1484 (D.C.Cir.1984), or by making possible a disposition by the agency that will "obviate the need for judicial decision on this issue," *Randolph-Sheppard Vendors of America v. Weinberger*, 795 F.2d 90, 105 (D..C.Cir. 1986).

A number of recent cases in this circuit have addressed the proper application of the exhaustion doctrine to a constitutional challenge to agency process. *See, e.g., Ticor Title Ins. v. Federal Trade Comm'n*, 814 F.2d 731 (D.C.Cir. 1987); *Hastings v. Judicial Conference of the United States*, 770 F.2d 1093 (D.C.Cir. 1985); *Andrade v. Lauer*, 729 F.2d 1475 (D.C.Cir. 1984). Nothing in the panel or concurring opinions in these cases justifies requiring further exhaustion by appellants here. Unlike in *Hastings* and *Ticor* (in which

plaintiffs were required to exhaust) and *Andrade* (in which plaintiffs were allowed to go forward with their pure constitutional challenge without further exhaustion), this court's review interrupts no ongoing administrative procedures involving members of the appellant class. Appellant patients sue to avoid certain administrative procedures at the outset. Even if we agreed that PRO approval of an individual patient's application "moots" the controversy as to that patient, further administrative process would not moot the challenge for other patients, because most will be denied.

Moreover, this is not a case where an individual patient's receipt of PRO approval will moot all his constitutional claims. By being forced to submit to PRO review, a patient suffers a discrete violation of his constitutional rights. By contrast, the plaintiffs in *Andrade*, *Ticor*, and *Hastings* claimed that the agencies seeking to determine plaintiffs' rights did so without constitutional authority. *See, e.g., Hastings*, 770 F.2d at 1099-1103 (federal judge sought to enjoin an investigation of his judicial conduct on the ground, *inter alia*, that the investigative body violated the constitutional principle of separation-of-powers). Unlike our appellants, these plaintiffs were not threatened with irreparable injury of constitutional dimension to their rights simply by being forced to submit to the complained-of-procedures.

Agency action therefore cannot secure the relief appellants here request or protect them from the injury they seek to avoid. In this sense, the administrative remedy is inadequate, *see Randolph-Sheppard*, 795 F.2d at 107 ("the relief [the agency] will provide through its action will not be sufficient to right the wrong"), and exhaustion would be futile. Also, this court has no interest in postponing consideration of the privacy claim to "gain[ ] a better perspective on the exact nature of the administrative process being challenged." *Ticor Title*, 814 F.2d at 743 (Edwards, J., separate

opinion). Because appellants maintain that any intrusion at all is intolerable, the court need only know that an outside body seeks to interfere with the doctor-patient relationship. In sum, postponement of review will serve none of the purposes of the exhaustion doctrine. We hold that the privacy challenge is ripe for this court's review.

### 2. *Ripeness of "liberty" claims*

Appellants assert that the "near-absolute" prohibition on Medicare patients' employment of an assistant cataract surgeon is a direct interference with their liberty rights. We express no opinion as to the merits of appellants' claim of violation of liberty rights because we find the issue not currently ripe for review.

Our conclusion that this claim is not ripe depends on our reading of relevant case precedent. We do not purport to address the difficult question of whether regulations of this type can ever give rise to a constitutional violation of liberty rights. We think that appellants' statement of a colorable claim of due process violation depends on showing, at a minimum, that the state's interference with an economic or medical choice has dire personal consequences. Apart from any theoretical difficulties in applying case authority dealing with direct bodily interference in this context, appellants' claim must fail at the outset absent evidence that the challenged regulation restricts access to treatment indispensable to a patient's life, health, or sight in a way that "shocks the conscience." *Rochin v. California*, 342 U.S. 165, 172, 72 S.Ct. 205, 209, 96 L.Ed. 183 (1952); *see also Garcia v. Miera*, 817 F.2d 650, 653-56 (10th Cir.1987) ("substantive due process" may protect against government action directly resulting in severe injury), *cert. denied*, —— U.S. ——, 108 S.Ct. 1220, 99 L.Ed.2d 421 (1988); *Hall v. Tawney*, 621 F.2d 607, 613 (4th Cir.1980) ("substantive due process is concerned

with violation of personal rights of privacy and bodily security of * * * [severe] magnitude * * * disproportionate to the need presented."); *cf. Doe v. Bolton*, 410 U.S. 179, 223, 93 S.Ct. 739, 755, 35 L.Ed.2d 201 (1973) (White, J., dissenting) (suggesting that the right to abortion is constitutionally protected whenever required to avoid "substantial hazards to either life or health"); *Roe v. Wade*, 410 U.S. 113, 173, 93 S.Ct. 705, 737, 35 L.Ed.2d 147 (1973) (Rehnquist, J., dissenting) (even barring strict scrutiny, an abortion statute endangering the life of the mother "would lack a rational relation to a valid state objective").

We think it clear that a claim that turns on whether the statutory scheme operates to endanger patients is not currently ripe for review. We are aware of appellants' allegation that *every* patient, regardless of pre-existing risk factors, is exposed to a significantly greater chance of unforeseen, dangerous complications without a second surgeon. It may be, however, that only certain types of patients incur the significant risk without a second surgeon that constitutes legally cognizable injury. Whether patients at risk of harm are in fact exposed to danger depends on whether the PROs apply the guidelines strictly or leniently. Although the guidelines list criteria for disapproval, it is not possible to glean from the face of the guidelines how each patient will fare. The record indicates that patients in California not meeting the listed criteria may appeal for an individualized review. Thus, patients must at least proceed through the stage of application to the PRO and denial of their claims if a court is to consider fully their due process argument.

We do not think that the hardship to patients incurred by this requirement outweighs the importance of developing the concrete record of enforcement practice indispensable to proper judicial consideration of the issue. Moreover, proceeding through this approval application stage does not

present patients with the dilemma of foregoing a benefit or risking sanctions. *See Gardner v. Toilet Goods Ass'n*, 387 U.S. 167, 172, 87 S.Ct. 1526, 1529, 18 L.Ed.2d 704 (1967). Enforcement of § 9307(c) takes place in two stages. Patients can challenge the statute in court after the applications for approval are denied. They need not engage the CAS in defiance of the disapproval before seeking review. Because the hardship of submitting to PRO procedures, which occasions little delay, does not outweigh this court's interest in postponing review, we hold that exhaustion is required.

## V. The Merits

[7] Having decided that appellants' privacy challenge is ripe for review, we address whether appellants assert constitutional interests infringed by § 9307(c). We disagree that the constitutional right to privacy comprehensively protects all choices made by patients and their physicians or subjects to "strict scrutiny" all government interference with choice of medical treatment. There is no basis under current privacy case law for extending such stringent protection to every decision bearing, however indirectly, on a person's health and physical well-being. Furthermore, the problem of determining what kinds of decisions qualify as "medical decisions" eligible for such protection demonstrates that appellants' contentions provide no manageable constitutional standard.

Appellants place great emphasis on *Roe v. Wade* and its progeny as supporting a comprehensive right of privacy protecting every physician-patient decision. They point to a number of passages in these decisions that speak of a woman's right to seek and follow the advice of her physician without state-mandated intrusion or interference. *See Doe v. Bolton*, 410 U.S. 179, 195-200, 93 S.Ct. 739, 749-51, 35 L.Ed.2d 201 (1973) (striking down hospital committee and second phy-

sician approval requirement for abortions as facially invalid); *Planned Parenthood v. Danforth*, 428 U.S. 52, 67-75, 96 S.Ct. 2831, 2840-44, 49 L.Ed.2d 788 (1976) (invalidating spousal and parental consent requirements); *Thornburgh v. American College of Obstetricians and Gynecologists*, 476 U.S. 747, 106 S.Ct. 2169, 2180-2181, 90 L.Ed.2d 779 (1986) (holding that specification of information to be provided to pregnant women unconstitutionally interferes with abortion decision-making). Reliance on these cases is misplaced. The Constitution shelters the medical decision-making process in the context of abortion not because it is "medical," but as a means to the end of free reproductive self-determination or autonomy. Accordingly, the Court has struck down regulations that "plac[e] obstacles in the path of the doctor upon whom [the woman is] entitled to rely for advice in connection with her decision" precisely because those obstacles have an impact "upon the woman's freedom to make a constitutionally protected decision." *Whalen v. Roe*, 429 U.S. at 604-05 n. 33, 97 S.Ct. at 879 n. 33.

This line of cases addressing abortion thus provides no rationale for according heightened constitutional protection to decisions affected by these COBRA amendments. *Roe v. Wade* and its progeny represent an extension of the long-recognized constitutional protection for decision-making in the intimate and personal realms of "marriage, procreation, contraception, family relationships, and child-rearing and education." *Whalen v. Roe*, 429 U.S. at 600 n. 26, 97 S.Ct. at 877 n. 26 (quoting *Paul v. Davis*, 424 U.S. 693, 713, 96 S.Ct. 1155, 1166, 47 L.Ed.2d 405 (1976)). Admittedly, the categories of private life the Court deems deserving of constitutional shelter "do not always have easily ascertainable boundaries." *Thornburgh*, 106 S.Ct. at 2184. Nevertheless, a decision by this court to confer privacy protection on all medical determinations, no matter what their nature or conse-

quences, would require us to range far beyond the traditional purview of the Court's privacy jurisprudence.

Appellants would nonetheless have us enlarge the privacy doctrine by taking a broader view of its underpinnings. They note that the Supreme Court has struggled to define the contours of the right to privacy by inquiring into which rights and interests are "fundamental," "deeply rooted in this Nation's history and tradition," and "implicit in a concept of ordered liberty," such that "neither liberty nor justice would exist if they were sacrificed." *Palko v. Connecticut*, 302 U.S. 319, 326, 58 S.Ct. 149, 152, 82 L.Ed. 28 (1937). Appellants insist that a logical extension of these "fundamental" principles warrants privacy protection for all decisions relating to care of health and the fate of one's body, since these matters are as "intimate," "personal," and "fundamental" as the traditional concerns of privacy jurisprudence.

To buttress their thesis, appellants muster scattered cases, arising in disparate legal situations, which speak of a zone of privacy in the patient-physician relationship and which adumbrate, however peripherally, an individual autonomy interest in making decisions affecting the quality of life. *See, e.g., Whalen v. Roe*, 429 U.S. at 600, 97 S.Ct. at 877 (suggesting a constitutional interest in independent decision-making in "matters vital to the care of * * * health"); *Andrews v. Ballard*, 429 F.Supp. 1038 (S.D.Tex.1980) (patients' constitutional privacy interests infringed by statute limiting who may practice acupuncture); *England v. Louisiana State Bd. of Medical Examiners*, 259 F.2d 626, 627 (5th Cir.1958) (with respect to due process challenge to state restrictions on chiropractors, "the state cannot deny to any individual the right to exercise a reasonable choice in the method of treatment of his ills"); *see also Doe v. Bolton*, 410 U.S. 179, 219, 93 S.Ct. 739, 755, 35 L.Ed.2d 201 (1973) (Doug-

las, J., concurring) (speaking of "the right to care for one's health and person and to seek out a physician of one's own choice" as encompassed by the right of privacy).

Appellants rely in particular on the Supreme Court's decision in *Whalen v. Roe*, 429 U.S. 589, 97 S.Ct. 869, 51 L.Ed.2d 64 (1976), for the proposition that the right of independent decision-making encompasses all medical matters. In that case, the Court upheld the constitutionality of a New York statute requiring the state to keep confidential records of dangerous and restricted drugs prescribed by physicians in the state. In the course of its discussion, the Court restated plaintiffs' argument that a privacy interest in "the making of important decisions independently" might include an interest in "making decisions about matters vital to the care of * * * health." *Whalen*, 429 U.S. at 600, 97 S.Ct. at 877. Because the Court decided that the statutory scheme was insufficiently intrusive to infringe patients' possible privacy interest in confidentiality, the Court did not rule on the merits of plaintiffs' contention. Thus *Whalen* fails to support appellants' thesis that the right to privacy prevents government interference with all medical decisions *per se*.

In sum, these decisions do not present a coherent body of law justifying the bold extension of privacy doctrine appellants recommend. There are additional reasons, however, why their arguments must be rejected. At the outset, it is altogether unclear what kinds of decisions appellants mean to include in the vague class of "medical decisions." On the basis of this conception of rights "fundamental to an ordered liberty," appellants would have us accord a dizzying range of decisions the same high degree of solicitude now reserved for first trimester abortions. Without further refinement, this class potentially includes vast areas of personal choice that might bear in some way on health or bodily well-being, covering decisions with dramatic and immediate

consequences for life and health as well as those motivated largely by personal taste or preference, convenience, or financial considerations.

Additionally, the "fundamental principles" to which appellants advert do not warrant constitutional shelter for medical decision-making as a generic category. At times, appellants speak of a fundamental interest in preserving health and life. *See, e.g.*, W. Blackstone, *Commentaries* 1:120–41 (1765), reprinted in *The Founders' Constitution* at 390–91 ("[T]he preservation of a man's health from such practices as may prejudice or annoy it * * * are rights to which every man is intitled [sic] * * *.") It is immediately apparent that such a principle cannot justify a blanket right to obtain without any government interference every and any kind of treatment that might be available and that a physician might recommend. Although many medical decisions are ostensibly made to promote health, patients and doctors often choose among more or less equivalent options with largely unknown or unpredictable consequences. Not all choices are *indispensable* to the preservation of health or represent a clearly preferable medical alternative. Thus, even if there is some "right" to protect health, such a right does not protect from regulatory interference every course of action undertaken by doctor and patient.

We doubt, in addition, that appellant can seek to expand the privacy doctrine on the basis of a general principle that all decisions relating to the disposition of one's body are "fundamental" and may not ordinarily be subject to government interference. Case precedent makes clear that not every decision relating to the body or bodily integrity is sufficiently intimate and personal to merit enhanced protection. For example, the Supreme Court has not recognized that the decision to reject vaccination implicates a "fundamental interest," although bodily invasion and medical treatment are

unavoidably involved. *See Jacobsen v. Massachusetts*, 197 U.S. 11, 25 S.Ct. 358, 49 L.Ed.2d 643 (1905). In *Schmerber v. California*, 384 U.S. 757, 86 S.Ct. 1826, 16 L.Ed.2d 908 (1966), the Court declined to adopt Justice Douglas' statement in dissent that "[n]o clearer invasion of [the] right of privacy can be imagined than forcible bloodletting of the kind involved here." *Id.* at 779, 86 S.Ct. at 1840 (Douglas, J., dissenting). *See also Breithaupt v. Abram*, 352 U.S. 432, 77 S.Ct. 408, 1 L.Ed.2d 448 (1957); Comment, *A Taxonomy of Privacy: Repose, Sanctuary, and Intimate Decision*, 64 Calif.L.Rev. 1447, 1471–73 (1976). In short, there is no basis for demanding strict scrutiny for every government measure involving interference with the body. We conclude that the underlying interests appellants identify as fundamental do not justify special constitutional status for a general category of "medical decisions."

We do not rule out that a particular medical decision with regard to eyesight may, like the choice to terminate early pregnancy, be entitled to constitutional privacy protection. In the case of choosing the number of surgeons participating in a surgical procedure designed to save sight, however, the prerequisite to a successful privacy claim would be a definite showing of medical necessity and the unavailability of equally effective alternative therapy. Without this first step, it seems clear this treatment decision is insufficiently consequential to merit a high level of protection from governmental interference.

On a motion to dismiss by the opposing party, appellants are entitled to all inferences in their favor. In order to withstand a motion to dismiss a claim that privacy protection extends to decisions whether to engage an assistant cataract surgeon, we believe that appellants must, at a minimum, create a genuine issue of material fact as to medical necessity. They have not succeeded in doing this on the record

before us, since they offer only unsupported expert opinion. *See Merit Motors v. Chrysler Corp.*, 569 F.2d 666, 673 (D.C.Cir.1977); *accord Evers v. General Motors Corp.*, 770 F.2d 984, 986 (11th Cir.1985) ("a party may not avoid summary judgment solely on the basis of an expert's opinion that fails to provide specific facts from the record to support its conclusory allegations").

In the Inspector General's Report, HHS asserts that a CAS is often not medically necessary. Although the government offers no scientific or epidemiological "hard data," the Report does reveal that cataract surgery in many states is routinely performed without the assistance of another physician. These data support the government's opinion that a second surgeon is not medically necessary. In opposition to these conclusions, appellants introduce affidavits by interested physicians proclaiming that "two heads are better than one." The affiant physicians list complications that can arise during cataract surgery and baldly assert that only a trained physician can handle these challenges successfully. Without a CAS, these physicians opine, the patient is exposed to a definite, enhanced risk of blindness.

These professions of necessity and anecdotal individual cases fail to qualify as competent factual support for appellants' assertions. Appellants must adduce objective scientific data, such as statistically sound epidemiological studies, demonstrating that surgeon assistance at cataract surgery is indispensable to patient well-being. Moreover, appellants cannot rely on the available data on local practices to support their point. The fact that many ophthalmologists in New York and California routinely operate with a second surgeon is *not* competent proof that a second surgeon is medically necessary. Appellants have thus not created a material issue of fact as to whether the matter of engaging an assistant at cataract surgery rises to this magni-

tude or has this character for all patients or for any identifiable subgroup of patients. We conclude that the district court properly granted HHS' motion to dismiss this claim on the basis of the evidence presented.

In summary, we affirm the district court's denial of an injunction and dismissal of appellants' claim on the merits with respect to the privacy issues ripe for review as outlined above. We decline to conduct pre-enforcement review of appellants' remaining constitutional contentions and accordingly dismiss them as unripe.

*Judgment accordingly.*

STEPHEN F. WILLIAMS, Circuit Judge, concurring in part and dissenting in part.

I concur in the court's affirmance of the district court's dismissal of the complaint, and in its reliance on the doctrines of exhaustion and ripeness. I write separately to express my view that the two doctrines apply to different aspects of the case's prematurity, and to present a somewhat different understanding of the plaintiffs' claim on the merits from that stated by the court.

As the court's opinion explains, plaintiffs—individual ophthalmologists, their patients, and two ophthalmological professional organizations—sue the Secretary of Health and Human Services in order to challenge the constitutionality of § 9307(c) of the Consolidated Omnibus Budget Reconciliation Act of 1985, Pub.L. 99-272, 100 Stat. 194, codified at 42 U.S.C.A. § 1395u(k) (Supp.1988). While another portion of the Act restricts *Medicare funding* for an assistant surgeon in a cataract operation to instances where an insurance carrier or peer review organization has approved the use because of "the existence of a complicating medical condition," 42 U.S.C.A. § 1395y(a)(15) (Supp.1988), the challenged section imposes substantial penalties (fines and ineligibility for Med-

icare reimbursement) on a doctor who bills *a patient* for services provided without such approval. It thus restricts the ability of a cataract patient to use her *own* money to secure such additional protection as an assistant surgeon might provide. Plaintiffs raise no objection to Congress's decision as to what HHS will reimburse; they attack only the limit on an individual's ability to enter into private arrangements—free of any expense to the government—to employ extra services that would (arguably) reduce the risks of losing his or her eyesight.

I

Exhaustion and ripeness advance substantially identical interests: (1) judicial economy (the proceedings before the agency may give the plaintiffs victory and thus moot the dispute); (2) agency autonomy (the agency's proceedings permit it to develop both a factual record and its own understanding and articulation of the issues); and (3) the proper functioning of the judiciary (judicial non-involvement until the conclusion of agency proceedings prevents the courts from becoming entangled in "abstract disagreements over administrative policies" unfit for judicial review). *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148, 87 S.Ct. 1507, 1515, 18 L.Ed.2d 681 (1967). See also *McKart v. United States*, 395 U.S. 185, 193-94, 89 S.Ct. 1657, 1663, 23 L.Ed.2d 194 (1969) (reviewing purposes of exhaustion doctrine); *American Trucking Ass'ns v. ICC*, 747 F.2d 787, 789-90 (D.C.Cir.1984) (ripeness). The clearest (and perhaps the only) difference between the doctrines is that exhaustion addresses the *plaintiff's* failure to employ available avenues of administrative relief, while ripeness addresses the status of *agency* activity, namely, the extent to which it has actually enforced its policies.

The two doctrines in this case apply to different features of prematurity. Exhaustion is relevant to the absence of any

evidence in the record that any plaintiff has applied for authorization to use an assistant surgeon and been denied. Ripeness applies to the failure of HHS (so far as appears) to impose § 1395u(k) penalties on any doctor for billing a patient for the services of an unapproved assistant surgeon.

Exhaustion first. Because the record contains no evidence of a denied application for carrier or PRO approval, we have some uncertainty as to how restrictive the carriers and PROs may be. See Maj.Op. at 1388. A clearer picture of the severity of the challenged statute would aid judical review: the more stringent the PROs and carriers, the heavier the burden imposed by the statute on the plaintiff patients' ability to use their own resources to protect their health.

In all candor, however, I think we should acknowledge that the rejection of a few applications will shed only a dim light on the issues here. Standing alone, one denied application would satisfy the exhaustion requirement, but it would mark out merely one point in the border between the accepted and the rejected; it would not define the border. More specifically, 42 U.S.C.A. § 1395y(a)(15) itself makes clear that carriers and PROs are not to authorize a second surgeon in the absence of a "complicating medical condition," i.e., some *special* indicator that an assistant surgeon's help would be useful. Thus complete exhaustion cannot significantly close the gap between the parties; 42 U.S.C.A. § 1395y(a)(15) appears to preclude the defendant from accepting in the slightest degree plaintiffs' belief that the presence of an assistant surgeon is always a wise precaution, even in the absence of any specific indicators. Accordingly, I believe that the case for requiring exhaustion is marginal.

Ripeness, as I have said, is implicated by HHS's having so far not enforced 42 U.S.C.A. § 1395u(k) against any doctors. The statute imposes the penalties when a doctor "bills" a Medicare patient for the services of an unapproved assis-

tant surgeon. As the court notes, the stated purpose is to protect beneficiaries from additional out-of-pocket costs. Maj.Op. at 1382 (citing legislative history). This leaves various possible interpretations, and under *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984), of course, we would owe considerable deference to HHS's choice. For example, a patient who pays the doctor before the operation, without having ever been "billed," will necessarily have confronted the choice in a starker, more concrete way than one who responds to billing after the operation. If the pre-paying patient has also been informed that the carrier's or PRO's denial of approval manifests his government's considered judgment that under the circumstances the expense is a waste (either in the sense of not being worth the cost, or perhaps in the stronger sense of not being worth anything), penalties hardly seem necessary to advance consumer-protection interests as they are normally conceived.

The closest HHS has come to passing on this issue takes the form of a statement of Thomas G. Morford, acting director of HHS's Health Standards and Quality Bureau, and Richard P. Kusserow, inspector general. The statement took the form of a question and answer published in *Argus*, a newsletter for ophthalmologists, in September 1986:

> Will Medicare patients have the freedom of choice to pay for a second surgeon?
>
> As we read the statute, it does not appear to exclude voluntary payment from the scope of the prohibition. Presumably, Congress was aware that patients are not usually in a position to disagree with the advice of their physicians, so that it would be impossible to determine whether a patient's decision was indeed "voluntary."

Plantiffs' Exhibit 2.

The statement leaves obscure to what extent the authors intend the second sentence to undermine the message of the first. (Nor does the record clearly indicate their authority to

speak for HHS.) At least a possible construction would be that the penalties do not apply to a doctor who received payment from a patient (1) who was never billed (thus escaping the literal language of § 1395u(k) ), (2) who paid in advance, and (3) who received full disclosure of the sort suggested above. So interpreted, the statue would impose a far less severe burden on plaintiffs' interests than if it were read as universally banning payments. Accordingly, because there has been neither enforcement nor any other authoritative indication of HHS's detailed intentions as to the application of § 1395u(k), adjudication now risks precisely the entanglement in indeterminate administrative policy decisions that the ripeness requirement is designed to prevent.

Plaintiffs invoke *Doe v. Bolton*, 410 U.S. 179, 188, 93 S.Ct. 739, 745, 35 L.Ed.2d 201 (1973), in which the Court allowed pre-enforcement review of Georgia's anti-abortion statute at the behest of physicians. But there the Court perceived no ambiguity in the statute that had a potential for altering the outcome of the constitutional issue. (I put aside the complications entailed by *Doe's* involving enforcement of a state criminal statute.) Here the unsettled issues of statutory interpretation render plaintiffs' constitutional claim unfit for judicial review.

Even if the issue presented were fit for judicial review, established ripeness law prevents pre-enforcement review unless failure to review would pose a hardship to parties. *Abbott Laboratories v. Gardner*, 387 U.S. 136, 149, 87 S.Ct. 1507, 1516, 18 L.Ed.2d 681 (1967). (For a limited exception, inapplicable here, see *Eagle-Picher Industries, Inc. v. EPA*, 759 F.2d 905 (D.C. Cir.1985) ). Such a hardship could occur if a doctor could obtain no authoritative advance reading from the Department as to its view of the statute's application to receipt of money under specific circumstances: the doctor would be required either to forego the transaction or to risk

the penalties authorized by § 1395u(k). A hardship for plaintiff patients could flow from this dilemma—inability to find a doctor willing to engage a second surgeon.

Thus, while hardship normally derives from parties' inability to secure a *judicial* hearing, here its primary source would be inability to obtain authoritative *administrative* rulings. But plaintiffs do not claim such rulings are unavailable. *Cf. National Automatic Laundry and Cleaning Council v. Shultz*, 443 F.2d 689 (D.C.Cir.1971) (authoritative, judicially reviewable advice provided in correspondence between trade association and Federal Wage and Hour Administrator). Accordingly, even if the constitutional issue posed were fit for judicial review, plaintiffs' hardship assertions are weak.

II

The court finds neither exhaustion nor ripeness a bar to adjudication of what it characterizes as plaintiffs' privacy claim, framed by the court as relating to an "interest in avoiding the approval requirement at its inception, as well as in obtaining the service." Maj.Op. at 1387. The court differentiates this claim from what it characterizes as plaintiffs' assertion of a "liberty" interest "in *procuring* the treatment of choice." Maj.Op. at 1383 (emphasis in original). The court characterizes the first claim, *so articulated*, as posing a "facial" challenge to § 1395u(k), a pure legal issue independent of the stringency of PRO or carrier review, Maj.Op. at 1383, and of the facts regarding the utility of the second surgeon. On this basis it finds the exhaustion and ripeness doctrines satisfied with respect to that claim.

My difficulty is that I do not believe plaintiffs have posed any such claim. So far as I can determine, there is a unified claim, which may best be characterized as resting in the plaintiff patients' interest in autonomy. (*Roe v. Wade*, 410 U.S. 113, 93 S.Ct. 705, 35 L.Ed.2d 147 (1973), and kindred

cases employ the term "privacy," but autonomy seems more apt to describe the individual's interest in making those decisions which affect only him or her (plus any others participating voluntarily).) So far as I can determine, this claim is not independent of the facts regarding the possible value of the uses of an assistant surgeon in unapproved situations; I do not understand plaintiffs to claim that they would have a constitutional claim if it were stipulated that a second surgeon contributed no increment in safety whatsoever in the unapproved situations. Nor am I able to perceive any claim independent of the extent of the practical burden imposed by § 1395u(k) (as it may prove to be interpreted by HHS). Accordingly, I cannot join the court in carving out any pure legal issue that surmounts exhaustion and ripeness.

The above deals with the court's rejection of a claim that I believe plaintiffs never made. No harm done. But the court's subdivision of plaintiffs' claim has a troubling side effect. It has led the court into a characterization of the remainder of plaintiffs' claim—what I regard as their sole claim—that appears to divest it of its autonomy values. Thus, the court analyzes what it sees as the second or "liberty" claim solely by reference to such cases as *Rochin v. California,* 342 U.S. 165, 72 S.Ct. 205, 96 L.Ed. 183 (1952), involving forcible government invasions of the individual's body, made in the interest of discovering criminal conduct and judged by the Court in terms of whether the government's act "shocks the conscience," *id.* at 172, 72 S.Ct. at 209. See Maj.Op. at 1388. This further leads the court to suggest that plaintiffs could prevail on the issue only by proving that the second surgeon's presence (in unapproved instances) was "*indispensable* to the preservation of health or represent[ed] a clearly preferable medical alternative," *id.* at 1390 (emphasis in original), or that the second surgeon was "a medical necessity," *id.* at 1391, or "medically necessary," *id.*

As exhaustion and ripeness aim to avoid premature judicial pronouncements, we should not get too far into the unaddressed claim. I will follow the majority only a short way into the thicket. § 1395u(k) restricts individuals' ability to decide for themselves the sort of medical care they may select in self-financed transactions with physicians. The *sole* interest asserted in favor of the restriction is the interest in preventing individuals from being harmed by making unwise expenditures of their own money; there is no claim that the presence of a second surgeon ever makes a cataract operation more risky. Thus the state interest is not only paternalistic, but lies solely in protecting pocketbook interests of the supposed patient beneficiaries.[1]

Let us consider two possible sets of facts: (1) No reasonable person could conclude that the second surgeon *ever* (in the unapproved cases) enhanced the patient's chances of retaining his eyesight. Here, as I've suggested, I believe that even plaintiffs would say they had no claim.

(2) In the unapproved cases the average incremental value of the second surgeon is less than its average cost (about $286 according to plaintiffs), but not necessarily much less. This would certainly explain Congress's unwillingness to provide insurance coverage for such operations. But an individual, fully informed about the costs and potential risk reduction, could reasonably decide to pay the extra amount. Averages, after all, are made up of individual figures, many or most of which deviate from the average. Moreover, the value a person attaches to preservation of eyesight is highly subjective. Suppose her vocation or interests specially de-

[1] Of course extravagant expenditures on health may in some instances affect health adversely, by foreclosing expenditures on items—higher quality food, shelter, recreation, etc.—that would have contributed more to the individual's health than the direct expenditure thereon. See generally Aaron Wildavsky, Searching for Safety (1988).

pend on sight—an artist (or a lawyer). Or suppose he was very rich, so that the marginal value of the $286 was very slight? Finally, even an individual patient for whom the *expected value* of the second surgeon (i.e., the value of the benefit under each of the various possible eventualities, weighted for the probability of each eventuality) is less than the cost may be willing to retain a second surgeon; he would do so for the same reason that people buy insurance—to reduce the variability of possible outcomes.

If the average value of the second surgeon is less than the cost, it would be hard to characterize the second surgeon as a "medical necessity," but it is far from clear to me that the invasion of individual autonomy would be constitutional. Accepting *arguendo* the majority's view that the Supreme Court will not place a person's ability to preserve her eyesight on the same lofty plane as her ability to abort a fetus, see *Roe v. Wade*, 410 U.S. 113, 93 S.Ct. 705, 35 L.Ed.2d 147 (1973), I wonder whether the state may prohibit a person from investing $286 in a health measure merely because its average incremental value is only, say, $280. What if its average incremental value is $50?

Nor am I clear, insofar as facts as to the utility of the second surgeon bear upon the constitutional issue, where the burden of proof lies. Normally of course a statute enjoys a presumption of constitutionality, so that one assailing it must establish such facts as may be necessary to undermine that presumption. But see *Doe v. Bolton*, 410 U.S. 179, 195, 93 S.Ct. 739, 749, 35 L.Ed.2d 201 (1973) (invalidating requirement that abortions be performed in a fully licensed hospital, as state failed to establish that only hospitals satisfied its interest in protecting the patient's health).

Clearly the facts may vary with infinite gradations. We have no way of knowing what may be proven by the statistical data for which the court rightly calls. Maj.Op. at 1391.

As a society we mandate in some situations the expenditures of billions of dollars per life expected to be saved. See, e.g., John A. Morrall III, A Review of the Record, *Regulation* (Nov/Dec 1986) 25, 30 (citing estimated cost of $72 *billion* dollars per life saved by proposed formaldehyde regulations). By what criteria could an individual be deemed irrational for wishing to spend $286 to reduce the risk of losing her eyesight by one-in-100,000? by one-in-a-million? If such an expenditure is not irrational, can Congress obstruct it solely on the basis of an asserted interest in consumer protection? Compare *Rutherford v. United States*, 616 F.2d 455 (10th Cir.1980) (upholding Food and Drug Administration's denial of approval of laetrile as a permissible "new drug" under 21 U.S.C. § 355 (1982), where FDA found insufficient evidence that it would have "the effect it purports or is represented to have"), with *England v. Louisiana State Board of Medical Examiners*, 259 F.2d 626, 627 (5th Cir.1958) (while state may outlaw "witch doctors, voodoo queens, bee stingers, and various other cults which no reasonably intelligent man would choose for the treatment of his ills," chiropractors are entitled to a chance to prove that "a reasonable man might . . . intelligently choose a chiropractor").

To repeat, I do not pass on these issues. By the same token, I most emphatically do not join the court in its suggestions that plaintiffs' autonomy claim can be validated only if they establish that the presence of the second surgeon in unapproved cases is "necessary."

APPENDIX B

# United States Court of Appeals
## FOR THE DISTRICT OF COLUMBIA CIRCUIT

Filed December 2, 1988
Nos. 87-5057 and 87-5065

NEW YORK STATE OPHTHALMOLOGICAL SOCIETY, *et al.*,
APPELLANTS

v.

OTIS R. BOWEN, SECRETARY OF H.H.S.
APPELLEE

On Appellants' Suggestion for Rehearing *En Banc*

*Rex E. Lee, Jack R. Bierig* and *David F. Graham* were on appellants' suggestion for rehearing *en banc*.

Before: WALD, *Chief Judge*, ROBINSON, MIKVA, EDWARDS, RUTH B. GINSBURG, STARR, SILBERMAN, BUCKLEY, WILLIAMS, D.H. GINSBURG and SENTELLE, *Circuit Judges*.

ORDER

Appellants' Suggestion for Rehearing *En Banc* has been circulated to the full court. No member of the Court requested the taking of a vote thereon. Upon consideration of the foregoing it is

ORDERED, by the Court *en banc*, that the suggestion is denied.

FOR THE COURT:

CONSTANCE L. DUPRE
Clerk

Circuit Judge Robinson did not participate in the foregoing order.

Circuit Judge Williams filed the attached statement concurring in the denial of rehearing en banc.

WILLIAMS, *Circuit Judge, concurring in the denial of rehearing en banc:* Appellants have suggested rehearing *en banc,* objecting to the panel majority's statement that a privacy claim—framed by the panel as a facial attack on the statutory approval requirement *per se,* Maj. Op. at 14—cannot prevail because the appellants failed to make a "definite showing of medical necessity," *id.* at 24. As I read the Suggestion of Appellants for Rehearing *en banc,* however, it confirms my prior understanding that they have made no facial attack; they never objected to the approval requirement *per se,* detached from the actual prospect of losing access to a second surgeon. Compare Suggestion of Appellants at 7 n.8 with Concurring Op. at 6-7. The seriousness of that prospect was unclear enough to lead both the majority and me to conclude that the case was not ripe. Accordingly, I do not believe that the case represents a holding of any kind on the legal issue that ultimately concerns appellants: the scope of any constitutional limits on the federal government's power to substantively obstruct patients' access to medical services that they reasonably deem valuable. Taking this view of the case, I have not called for a court vote on appellants' suggestion.

## APPENDIX C

## UNITED STATES DISTRICT COURT
## FOR THE DISTRICT OF COLUMBIA

| | |
|---|---|
| NEW YORK STATE OPHTHALMOLOGICAL SOCIETY, ET AL., *Plaintiffs* *v.* OTIS R. BOWEN, SECRETARY OF HEALTH AND HUMAN SERVICES, *Defendant* | C.A. No. 86-1926 |

### ORDER

Upon consideration of Plaintiffs' Motion for Preliminary Injunction, Defendant's Motion to Dismiss, the oppositions filed thereto, oral argument heard March 2, 1987, and the record in this case, it is

ORDERED by the Court that the preliminary injunction is DENIED.

The Court disagrees with plaintiffs' contention that the statutory scheme violates the patients' constitutional rights to privacy, liberty and association and the physicians' constitutional rights to association, free speech and due process. The withdrawal of federal funds does not penalize plaintiffs' exercise of fundamental rights. Section 9307 of the Consolidated Omnibus Budget Reconciliation Act of 1985 does not interfere with plaintiff physicians' right to practice their profession or with plaintiff patients' right to make decisions regarding their own health care. *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986). The statute is rationally re-

lated to a legitimate government purpose—the prohibition of expenditure of federal funds determined to be medically unnecessary, while protecting medicare beneficiaries.

Accordingly, it is

ORDERED that Sec. 9307 of the Consolidated Omnibus Budget Reconciliation Act of 1985, 42 U.S.C. Secs. 1395y(a)(15) and 1395u(k), will take effect as scheduled and govern cataract surgery performed on or after March 1, 1987.

SO ORDERED, this 10th day of March, 1987.

GEORGE H. REVERCOMB

George H. Revercomb, Judge

3/10/87

Date

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## APPENDIX D

## UNITED STATES DISTRICT COURT
## FOR THE DISTRICT OF COLUMBIA

| | |
|---|---|
| NEW YORK STATE OPHTHALMOLOGICAL SOCIETY, ET AL.,<br>*Plaintiffs*<br>*v.*<br>OTIS R. BOWEN, SECRETARY OF HEALTH AND HUMAN SERVICES,<br>*Defendant* | C.A. No. 86-1926 |

### JUDGMENT ORDER

In accordance with this Court's order of March 10, 1987, denying plaintiffs' motion for preliminary injunction it is hereby ordered that plaintiff's motion for preliminary injunction is DENIED, defendant's motion to dismiss is GRANTED and it is further,

ORDERED that judgment be entered in favor of defendants

GEORGE H. REVERCOMB

George H. Revercomb, Judge

3/12/87

Date

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Supreme Court, U.S.
FILED
MAY 10 1989
JOSEPH F. SPANIOL, JR.
CLERK

No. 88-1446

# In the Supreme Court of the United States

OCTOBER TERM, 1988

NEW YORK STATE OPHTHALMOLOGICAL SOCIETY, ET AL., PETITIONERS

*v.*

LOUIS W. SULLIVAN, SECRETARY OF HEALTH AND HUMAN SERVICES

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT*

## BRIEF FOR THE RESPONDENT IN OPPOSITION

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BEST AVAILABLE COPY

## QUESTIONS PRESENTED

Section 9307(c)(2) of the Consolidated Omnibus Budget Reconciliation Act of 1985, 42 U.S.C. 1395u(k)(1) and (2) (Supp. IV 1986), prohibits physicians from billing Medicare patients for services of an assistant cataract surgeon ("CAS") unless those services have been approved by an insurance carrier or designated state Peer Review Organization. The questions presented are:

1. Whether petitioners' claim that Section 9307(c)(2) violates patients' constitutional right to choose medical treatment is ripe when neither the patients in this case nor their physicians have made any effort to obtain approval of the use of a CAS.

2. Whether Section 9307(c)(2) is unconstitutional on its face because it deprives patients of their right to choose medical treatment.

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# In the Supreme Court of the United States

OCTOBER TERM, 1988

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No. 88-1446

NEW YORK STATE OPHTHALMOLOGICAL SOCIETY, ET AL., PETITIONERS

*v.*

LOUIS W. SULLIVAN, SECRETARY OF HEALTH AND HUMAN SERVICES

---

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT*

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## BRIEF FOR THE RESPONDENT IN OPPOSITION

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### OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-35a) is reported at 854 F.2d 1379. The opinion of the district court (Pet. App. 38a-39a) is unreported.

### JURISDICTION

The judgment of the court of appeals was entered on August 19, 1988. The court of appeals denied rehearing on December 2, 1988 (Pet. App. 36a-37a). The petition for a writ of certiorari was filed on March 2, 1989. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

## STATEMENT

Petitioners are prospective cataract surgery patients in New York and California, ophthalmologists practicing in those two states, and their state professional associations. They filed this action for declaratory and injunctive relief in the United States District Court for the District of Columbia, challenging the constitutionality of Section 9307(c)(2) of the Consolidated Omnibus Budget Reconciliation Act of 1985, 42 U.S.C. 1395u(k)(1) and (2) (Supp. IV 1986). That provision forbids a physician from billing a Medicare beneficiary directly for the costs of an assistant cataract surgeon (CAS) unless those services have been approved by an insurance carrier or designated state Peer Review Organization (PRO).[1] None of the petitioners sought approval for the use of a CAS in a cataract surgery prior to filing this lawsuit.

2. The district court denied petitioners' motion for a preliminary injunction (Pet. App. 38a-39a) and granted the government's motion to dismiss the complaint (*id.* at 40a). The court rejected petitioners' contentions that the statutory prohibition violated the "patients' constitutional rights to privacy, liberty and association and the physicians' constitutional rights to association, free speech and due process" (*id.* at 38a).[2]

[1] Section 9307(c)(2)'s prohibition does not extend to instances where use of a CAS has been approved for Medicare reimbursement. Section 9307(a)(3), in turn, provides that Medicare reimbursement is allowed only where a PRO or a carrier acting on the Secretary's behalf finds that the use of a CAS is warranted because of a patient's complicating medical condition (see 42 U.S.C. 1395y(a)(15) (Supp. IV 1986)). Although PRO approval will normally occur prior to surgery, the procedures for approval also permit a PRO to approve the use of a CAS after surgery where use of a CAS occurred because an emergency arose during surgery.

[2] In this Court, petitioners are asserting an infringement only of patients' constitutional rights.

3. The court of appeals affirmed (Pet. App. 1a-35a). The court concluded that petitioners' claim that the statute deprived them of liberty without due process was not ripe for judicial review (*id.* at 17a-19a). According to the court, "patients must at least proceed through the stage of application to the PRO and denial of their claims if a court is to consider fully their due process argument" (*id.* at 18a). Although petitioners' privacy claim was held ripe for review (*id.* at 13a-17a), the court rejected that claim on the merits (*id.* at 19a-26a). The court concluded that there was no merit to petitioners' assertions that "the constitutional right to privacy comprehensively protects all choices made by patients and their physicians or subjects to 'strict scrutiny' all government interference with choice of medical treatment" (*id.* at 19a). The court reasoned that "[i]n the case of choosing the number of surgeons participating in a surgical procedure designed to save sight, * * * the prerequisite to a successful privacy claim would be a definite showing of medical necessity and the unavailability of equally effective alternative therapy" (*id.* at 24a). The court concluded that petitioners had failed to make such a showing in this case (*id.* at 24a-26a).

Judge Williams filed a separate opinion concurring in part and dissenting in part (Pet. App. 26a-35a). He disputed the majority's analysis of the merits of petitioners' constitutional claim but joined the court's judgment on the ground that the lawsuit was unripe in its entirety (*ibid.*).

## ARGUMENT

The decision of the court of appeals is correct and does not conflict with any decision of this Court or of any other court of appeals. Accordingly, further review is not warranted.

1. Petitioners' constitutional claims are not ripe. Petitioners contend that, by prohibiting a doctor from billing

a Medicare beneficiary for the costs of a CAS, Section 9307(c)(2) unconstitutionally deprives patients of their choice to obtain those services at their own expense. Since petitioners concede that their claim would be without merit if a CAS contributed no increment in safety in unapproved situations (Pet. 13 n.8), their constitutional claim is premature because no patient or physician in this case has sought approval from a PRO or a carrier for use of a CAS in a particular surgery. Unless and until such an application has been made and denied, the statute has not adversely affected the ability of any petitioner to obtain medical services. Judicial review of a constitutional challenge to Section 9307(c)(2) should await the development of such a concrete controversy. See *Williamson County Comm'n* v. *Hamilton Bank,* 473 U.S. 172, 199-200 (1985); *Abbott Laboratories* v. *Gardner,* 387 U.S. 136, 148-149 (1967).

2. The court of appeals, for this reason, concluded that petitioners' claim that they had been deprived of liberty without due process was not ripe for review (see Pet. App. 17a-19a). The court concluded, however, that petitioners' complaint raised a separate constitutional claim—based on their right to privacy—that was ripe for adjudication (see *id.* at 13a-17a): a claim that the very requirement of prior approval was, in itself, a violation of that right. Like Judge Williams (see *id.* at 31a-32a), we do not believe that any such distinct constitutional claim ripe for review can be fairly gleaned from petitioners' complaint.[3] But, in any event, further review is not warranted because

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[3] Petitioners do not embrace the court of appeals' suggested dichotomy between patients' privacy and liberty interests. They instead characterize the claimed constitutional right—the right to secure the services of a CAS—as either a "liberty or privacy interest" (see Pet. 14).

the court of appeals correctly rejected that privacy claim on the merits.

Contrary to petitioners' contention (Pet. 14-21), this Court has never swept into the constitutional right of privacy all choices concerning medical treatment made by patients and their physicians so as to subject to strict scrutiny any governmental interference with a person's choice of medical treatment. As the court of appeals explained (Pet. App. 14a-21a), "[t]here is no basis under current privacy case law for extending such stringent protection to every decision bearing, however indirectly, on a person's health and physical well-being. Furthermore, the problem of determining what kinds of decisions qualify as 'medical decisions' eligible for such protection demonstrates that [petitioners'] contentions provide no manageable constitutional standard" (*id.* at 19a).

The decisions of this Court cited by petitioners in support of their view (see Pet. 15-20) are not to the contrary. *Youngberg* v. *Romero,* 457 U.S. 307, 315-319 (1982), upon which petitioners rely (Pet. 14), concerned a mentally retarded individual who had been committed to a state institution; the constitutional claim asserted was the right to reasonable safety and freedom from physical restraint during the period of commitment.

Nor does this Court's decision in *Winston* v. *Lee,* 470 U.S. 753 (1985), also discussed by petitioners (Pet. 15-16), aid their cause. As petitioners acknowledge, *Winston* involved the wholly distinct issue whether the government could "*require* a medical procedure that could pose risks to the patient" (Pet. 16). The commonsense notion that "[a] compelled surgical intrusion into an individual's body * * * implicates expectations of privacy and security" (470 U.S. at 759) cannot, as petitioners suggest, be readily transformed into the far broader proposition that any matter implicating human health, including the ability to

choose medical treatment, similarly implicates fundamental constitutional concerns requiring heightened standards of judicial review.[4]

Petitioners' reliance (Pet. 16-18) on this Court's decisions arising in the abortion context is likewise misplaced. As the court of appeals explained (Pet. App. 20a), "[t]he Constitution shelters the medical decision-making process in the context of abortion not because it is 'medical,' but as a means to the end of free reproductive self-determination or autonomy."[5]

Finally, there is no merit to petitioners' claim (Pet. 20-21) that the court of appeals erred in upholding dismissal of their complaint on the ground that petitioners had failed to make the "definite showing" requisite "to a successful privacy claim * * * of medical necessity and the unavailability of equally effective alternative therapy" (Pet. App. 24a). Contrary to petitioners' assertion (Pet. 20), the court of appeals did not "confuse[ ] the question of the existence of a constitutionally protected interest with the question of whether that interest can be immunized from all government regulation" (*ibid.*). The court of appeals never purported to describe the universe of circumstances in which an individual's interest in health-related matters would be entitled to some weight in constitutional analysis. The court was instead addressing only

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[4] Similarly, the claim in *Washington* v. *Harper*, cert. granted, No. 88-599 (Mar. 6, 1989), currently pending before this Court, concerns the scope of a patient's right to *refuse* treatment that the State proposes to administer.

[5] For this reason, there is also no merit to petitioners' suggestion (Pet. 22-23) that this Court's decision to note probable jurisdiction in *Webster* v. *Reproductive Health Services*, No. 88-605 (argued Apr. 26, 1989), renders review here more appropriate. (In *Webster*, the Court has been asked to reconsider *Roe* v. *Wade*, 410 U.S. 113 (1973).)

the discrete instances in which the medical treatment decision might be sufficiently "consequential to merit a high level of protection from governmental interference" pursuant to strict scrutiny review (Pet. App. 24a).[6] Indeed, the only "interference" whose validity was at this point under consideration by the court was the statutory requirement of prior approval of a CAS. Because no showing of medical necessity had been made, and because this statutory requirement represents a reasonable effort by Congress to limit Medicare expenditures for routine cataract surgery without burdening Medicare beneficiaries, dismissal of petitioners' complaint was proper.

3. The petition does not present an issue of "national importance" warranting this Court's review at this time (see Pet. 21-23). The court of appeals' decision is the first in which such a constitutional challenge has been made to Section 9307(c)(2). Hence, no circuit conflict currently exists. Indeed, petitioners do not cite in the petition, nor are we aware of, any other court of appeals decision accepting a similar claim. There is no reason therefore to suppose that petitioners' novel theory of constitutional law raises a pressing issue requiring this Court's review.

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[6] Hence, petitioners are mistaken in their characterization of the court of appeals' decision as ruling "that the Constitution affords no protection to any patient treatment decisions other than those that are 'indispensable to patient well-being' " (Pet. 14 (quoting Pet. App. 25a)).

## CONCLUSION

The petition for a writ of certiorari should be denied.
Respectfully submitted.

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IN THE

# Supreme Court of the United States

OCTOBER TERM, 1988

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NEW YORK STATE OPHTHALMOLOGICAL SOCIETY, CALIFORNIA ASSOCIATION OF OPHTHALMOLOGY, *et al.*,
*Petitioners,*

v.

LOUIS W. SULLIVAN, Secretary,
United States Department of Health
and Human Services,
*Respondent.*

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**On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit**

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IN THE

# Supreme Court of the United States

OCTOBER TERM, 1988

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No. 88-1446

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NEW YORK STATE OPHTHALMOLOGICAL SOCIETY, CALIFORNIA ASSOCIATION OF OPHTHALMOLOGY, *et al.*,
*Petitioners,*

v.

LOUIS W. SULLIVAN, Secretary,
United States Department of Health
and Human Services,
*Respondent.*

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**On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit**

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## REPLY BRIEF OF PETITIONERS

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The statute at issue in this case, § 9307(c) of the Consolidated Omnibus Budget Reconciliation Act of 1985, 42 U.S.C. § 1395u(k), takes away patients' ability to choose, in conjunction with a qualified physician, a course of medical treatment which the government itself acknowledges is medically preferable and which is indisputably not harmful.[1] The majority opinion below held that

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[1] "Defendant does not deny that the attendance of an assistant specialist may be *preferable* in *any* [cataract] operation or that adverse medical consequences may otherwise result . . . ." Defendant's Opposition to Plaintiffs' Motion for Preliminary Injunction, p. 22 (emphasis supplied).

this deprivation does not implicate any constitutionally cognizable interests—and therefore does not require any balancing of governmental interests against patient interests—unless the treatment involved is proved "indispensable to a patient's life, health or sight." (Pet. App. 17a). This holding constitutes an unprecedented diminution of interests in personal security protected substantively by the Due Process Clause. Moreover, it conflicts with this Court's consistent recognition of those interests.

Significantly, respondent's effort to dissuade this Court from hearing this case is not premised on a different understanding of the impact of the statute on patient interests in medical decision-making and safety. Indeed, respondent himself frames the question presented as, "Whether Section 9307(c)(2) is unconstitutional on its face because it deprives patients of their right to choose medical treatment." Brief for the Respondent in Opposition ("Opp.") at (I). Respondent argues, however, that these patient interests—in diminishing risks to eyesight—are simply not of constitutional significance. It relies on the majority's extraordinarily cramped and erroneous view of the scope of patient interests entitled to constitutional consideration. This case thus squarely poses questions of the utmost importance regarding whether patients possess a constitutional interest in choosing a safer course of medical treatment and whether the strength of the government's reasons for restricting such a choice are of relevance and must be weighed. For the reasons set forth below and in the Petition, this case should be heard by this Court.

1. Contrary to respondent's first argument, this case is ripe for review. The challenged statute precludes Medicare patients from hiring a cataract surgical assistant ("CAS") without prior approval by a governmentally designated organization "based on the existence of a complicating medical condition." 42 U.S.C. § 1395y(a)(15). Petitioners, however, want to receive or provide

CAS services even in the absence of "a complicating medical condition." Their contention, as described by the court of appeals, is that "every patient, regardless of pre-existing risk factors, is exposed to a significantly greater chance of unforeseen, dangerous complications without a second surgeon" (Pet. App. 18a), because unpredictable emergency complications necessitating CAS services occur in approximately 3% of cataract surgeries. *See* Petition at 4-5 and n.2. In short, petitioners attack the appropriateness of the "complicating medical condition" standard at the outset because, as even the government has recognized (*see* Petition at 12), CAS services contribute in all cases to the incremental margin of safety—not merely in those cases where a complicating condition may exist.

As the majority opinion correctly noted, "How the PROs apply the guidelines concerning 'complicating medical conditions' or other factors that entitle patients to approval does not bear on whether the PROs should be making this inquiry in the first place." (Pet. App. 14a). Petitioners object to this medically inappropriate inquiry and to any resulting restriction on the provision of CAS services. It is therefore irrelevant to the ripeness of petitioners' claims that they have not gone through the approval process because the approval process itself is the subject of petitioners' objections. *Compare Doe* v. *Bolton*, 410 U.S. 179 (1973) (permitting challenge to statute by physicians whose patients had not yet applied to hospital committee for abortion approval or sought two-physician concurrence). Indeed, it would be utterly pointless to require petitioners to submit applications for approval articulating the medical view that *all* cataract surgies are inherently safer if accompanied by CAS services when the statute by its terms prohibits approval on such a basis. Unless the statute is to be rendered a nullity, universal approval will not be forthcoming.

The majority opinion recognized this reality, recognized that most applications for approval will be denied (Pet.

App. 16a), and proceeded to render a decision on the merits of petitioners' facial challenge. The impact of that erroneous decision on the merits cannot now be avoided by respondent's fallacious ripeness argument. Accordingly, the merits of this case are ripe for review by this Court.[2]

2. The majority below acknowledged that "the type of burden imposed on patients by this scheme . . . would not withstand scrutiny in the context of a recognized constitutional interest." (Pet. App. 9a). It held that patients have no "recognized constitutional interest" in choosing a safer medical procedure, however, unless the "treatment [is] indispensable to a patient's life, health or sight . . . ." (Pet. App. 17a; *see also* Pet. App. 24a-26a). Due to this holding, the majority did not address the nature or strength of the governmental interests alleged to justify § 9307(c) and did not weigh those interests against those of patients.

Respondent seeks to minimize the significance and extreme nature of this holding by claiming that the majority opinion did not actually describe the "circumstances in which an individual's interest in health-related matters would be entitled to some weight in constitutional analysis." (Opp. at 6). This revisionist interpretation fails to account for the majority's failure to balance the competing interests. Further, it is flatly contradicted by the majority opinion itself. In disposing of what it characterized as petitioners' "liberty" claims, the majority

[2] While deciding what it characterized as petitioners' "privacy" claim, the majority below also held that petitioners' "liberty" claim was not ripe, as respondent accurately notes. But as explained in our Petition, p. 10, this limited procedural holding was wholly derived from the majority's decision on the merits that only "indispensable" medical treatment rises to the level of a "legally cognizable" liberty interest. Respondent does not dispute this fact. "Ripeness" can hardly be a reason for avoiding review of the merits, however, when the "ripeness" determination itself rests on the same decision on the merits that is being challenged.

explicitly stated that any such claim would require "*at a minimum*" a showing "that the challenged regulation restricts access to treatment indispensable to a patient's life, health, or sight in a way that 'shocks the conscience.'" (Pet. App. 17a) (emphasis supplied). Similarly, in deciding petitioners' "privacy" claims the majority held that "*the prerequisite* to a successful privacy claim would be a definite showing of medical necessity." (Pet. App. 24a) (emphasis supplied). In sum, the majority *did* set a base-line test under which no constitutional weight attaches to patient interests in choosing a safer medical treatment except in extreme medical circumstances.

As explained in our Petition at 14-21, this Court's decisions squarely conflict with such an approach. In every case in which this Court has been confronted with a governmental action that directly threatens to impose a risk to an individual's health, even a slight or uncertain risk, this Court has recognized that important constitutional interests in personal security are implicated. *See, e.g., Thornburgh* v. *American College of Obstetricians and Gynecologists*, 476 U.S. 747, 768-69 (1986); *Winston* v. *Lee*, 470 U.S. 753, 767 (1985). Indeed, respondent is unable to cite any authority of this Court even suggestive of a contrary view, or supportive of the notion that no weighing of competing interests is necessary in such a circumstance.

Instead, respondent resorts to noting that the facts involved in these prior cases differ from those involved here. Opp. at 5-6. This is indisputable. In fact, § 9307 (c) is "unprecedented" (Petition at 12). Never to our knowledge has any governmental body sought to preclude private patient access to a medical procedure conceded to be medically "preferable." *See* p. 1, n.1, *supra*.

But while this case differs factually from those previously considered by this Court, there is no principled basis for distinguishing the patient interests at stake

here from the constitutional patient interests recognized by this Court in other settings. For example, it is true that *Youngberg* v. *Romeo*, 457 U.S. 307 (1982), concerned treatment of a mentally retarded individual in a state institution. Opp. at 5. But the historic "right to personal security" (*id.* at 315) recognized in that case, including a right to be free from endangering governmental actions, does not apply only to confined individuals. The "liberty" interests of the free populace are at least equal and are implicated by governmental action that prevents an individual from taking private steps to ensure health and safety, *i.e.*, in this case eyesight.[3]

Respondent's attempted distinction of *Winston* v. *Lee*, 470 U.S. 753 (1985), is similarly unavailing. That case involved a governmentally *compelled* medical procedure creating risks to health while this case involves a governmental *prohibition* on medical procedures that creates risks to health. In both cases, however, it is the patient's interest in preserving health and safety that is threatened, and it is governmental action that creates the threat. The fact that the form of the governmental action differs is irrelevant. *See* Petition at 16. Respondent has not replied to this analysis or suggested any principled basis for distinguishing between the two cases.

Respondent also attempts to distinguish *Thornburgh* v. *American College of Obstetricians and Gynecologists*, 476 U.S. 747 (1986), and the related cases discussed in the Petition at 16-18 and n.11, by reiterating the claim of the court of appeals majority that the protections afforded in *Thornburgh* are merely "a means to the end of free reproductive self-determination or autonomy." Opp. at 6. That

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[3] *See DeShaney* v. *Winnebago County Department of Social Services*, —— U.S. ——, 57 U.S.L.W. 4218, 4221 (1989) ("In the substantive due process analysis, it is the State's affirmative act of restraining the individual's freedom to act on his own behalf . . . which is the 'deprivation of liberty' triggering the protection of the Due Process Clause . . . .")

claim is simply wrong, however, as explained at length in the Petition at 16-18. *Thornburgh* dealt with a statute regulating medical techniques used in *post*-viability abortions. In the *post*-viability stage, a woman's interest in "free reproductive self-determination" is not protected, but her interest in preserving her health and life is. Accordingly, this Court's refusal to allow any *post*-viability "trade-off" that would require the woman to bear an increased medical risk is attributable to the protection of the woman's health interests, not to the end of free reproductive self-determination. Respondent simply ignores this analysis while offering none in its stead.

These cases are reflective of an unbroken chain of precedents, both in this Court and the lower courts, which have treated governmental infringements on patients' health and safety interests with the utmost seriousness. This is not to say that "any governmental interference with a person's choice of medical treatment" is "subject to strict scrutiny."[4] Opp. at 5. Rather, it suggests that a weighing of interests is appropriate, and that the nature of the interest asserted by the government is critical in this balancing.

It is one thing for the government to interfere with a medical choice in order to protect patient or community health. *See* Petition at 13, n.8, and 19-20. It is quite another thing for the government to interfere with a medical choice not to protect health but rather to prevent individuals from "unwisely" spending personal funds to lessen health risks (Pet. App. 33a)—especially where its intervention concededly increases risks to a patient's health. That is what the government has done here. The

[4] Although respondent also raises abstract concerns about what constitutes a "medical decision" (Opp. at 5), these concerns have no bearing on this case or its appropriateness for review. Petitioners here seek protection to choose a specific class of surgical services which are unquestionably medical in nature, and which bear directly on the extent of health risks in surgery.

majority below fundamentally erred by not treating such governmental action as implicating constitutional interests and therefore failing even to consider whether the government interests asserted are significant enough to justify the resulting threat to patient health.

3. This case presents an issue of national importance. It is no less important because the issue has not been adjudicated by another circuit. For the one million senior citizens who undergo cataract surgery annually and who are exposed to an increased risk of loss of an eye or other serious injury by § 9307(c), review of this matter cannot further be delayed.

## CONCLUSION

For the foregoing reasons and those stated in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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